Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		
Hypertensive heart disease									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Heart failures									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	1 (0.7)	1	0.6	1 (0.7)	1	0.6
35-<40	0			0			1 (1.0)	2	1.5
>=40	0			0			0		
Cardiac failure congestive									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	1 (0.7)	1	0.6	0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		
Cardiac failure acute									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6
35-<40	0			0			0		
>=40	0			0			0		
Left ventricular failure									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Myocardial disorders									
<30	0			0			1 (1.3)	1	1.0
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Cardiac hypertrophy									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Left ventricular hypertrophy									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Reproductive system and breast disorders									
<30	1 (1.5)	2	2.4	1 (1.5)	1	1.1	0		
30-<35	6 (3.7)	6	2.8	2 (1.4)	2	1.1	3 (2.2)	3	1.7
35-<40	4 (4.0)	8	6.1	5 (4.9)	5	3.6	4 (4.1)	6	4.6
>=40	4 (5.4)	4	3.9	4 (4.3)	4	3.2	2 (2.2)	2	1.6
Vulvovaginal disorders (excl infections and inflammations)									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	1 (1.0)	1	0.8	2 (1.9)	2	1.4	1 (1.0)	1	0.8
>=40	0			1 (1.1)	1	0.8	0		
Vulvovaginal pruritus									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Vulva cyst									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Vulval disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Vaginal disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		
Vaginal haemorrhage									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>=40	0			0			0		
Vulvovaginal dryness									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Menstrual cycle and uterine bleeding disorders									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	2	(2.0)	2 1.5	2	(1.9)	2 1.4	1	(1.0)	2 1.5
>=40	0			0			0		
Dysmenorrhoea									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Metrorrhagia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Oligomenorrhoea									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Menorrhagia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Menstruation irregular									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			1 (1.0)	2	1.5
>=40	0			0			0		
Sexual function and fertility disorders									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6
35-<40	1 (1.0)	1	0.8	1 (1.0)	1	0.7	0		
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	0		
Erectile dysfunction									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6
35-<40	1 (1.0)	1	0.8	1 (1.0)	1	0.7	0		
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	0		
Reproductive tract disorders NEC									
<30	0			1 (1.5)	1	1.1	0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	1 (1.0)	1	0.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Pruritus genital									
<30	0			1 (1.5)	1	1.1	0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Pelvic pain									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Breast disorders									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	1 (1.0)	1	0.8	0			1 (1.0)	1	0.8
>=40	0			1 (1.1)	1	0.8	0		
Breast mass									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			1 (1.1)	1	0.8	0		
Breast cyst									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Breast pain									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Menopause related conditions									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			1	(1.1)	1 0.8	0		
Atrophic vulvovaginitis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			1	(1.1)	1 0.8	0		
Uterine, pelvic and broad ligament disorders									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	0			0			1	(1.1)	1 0.8
Uterine polyp									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Adenomyosis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	0			0			0		
Endometriosis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Male reproductive tract infections and inflammations									
<30	0			0			0		
30-<35	2	(1.2)	2 0.9	0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	2	(2.7)	2 2.0	0			0		
Balanoposthitis									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	2	(2.7)	2 2.0	0			0		
Prostatitis									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Ovarian and fallopian tube disorders												
<30	0				0				0			
30-<35	0				0				0			
35-<40	1	(1.0)	1	0.8	0				0			
>=40	1	(1.4)	1	1.0	0				0			
Haemorrhagic ovarian cyst												
<30	0				0				0			
30-<35	0				0				0			
35-<40	1	(1.0)	1	0.8	0				0			
>=40	0				0				0			
Ovarian cyst												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	1	(1.4)	1	1.0	0				0			
Penile and scrotal disorders (excl infections and inflammations)												
<30	1	(1.5)	2	2.4	0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Penile erosion												
<30	1	(1.5)	1	1.2	0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Peyronie's disease									
<30	1 (1.5)	1	1.2	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Prostatic disorders (excl infections and inflammations)									
<30	0			0			0		
30-<35	2 (1.2)	2	0.9	0			1 (0.7)	1	0.6
35-<40	0			0			0		
>=40	0			0			0		
Benign prostatic hyperplasia									
<30	0			0			0		
30-<35	2 (1.2)	2	0.9	0			1 (0.7)	1	0.6
35-<40	0			0			0		
>=40	0			0			0		
Testicular and epididymal disorders									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (1.1)	1	0.8
Testicular disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (1.1)	1	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Blood and lymphatic system disorders									
<30	0			3 (4.4)	3	3.3	4 (5.2)	4	4.1
30-<35	4 (2.5)	4	1.9	6 (4.3)	7	4.0	2 (1.5)	3	1.7
35-<40	2 (2.0)	2	1.5	2 (1.9)	2	1.4	2 (2.1)	2	1.5
>=40	3 (4.1)	3	2.9	1 (1.1)	1	0.8	2 (2.2)	2	1.6
Anaemias nonhaemolytic and marrow depression									
<30	0			3 (4.4)	3	3.3	3 (3.9)	3	3.1
30-<35	4 (2.5)	4	1.9	5 (3.6)	6	3.4	2 (1.5)	2	1.1
35-<40	1 (1.0)	1	0.8	1 (1.0)	1	0.7	1 (1.0)	1	0.8
>=40	3 (4.1)	3	2.9	1 (1.1)	1	0.8	0		
Anaemia									
<30	0			3 (4.4)	3	3.3	2 (2.6)	2	2.0
30-<35	3 (1.8)	3	1.4	4 (2.9)	4	2.3	2 (1.5)	2	1.1
35-<40	0			1 (1.0)	1	0.7	0		
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	0		
Iron deficiency anaemia									
<30	0			0			1 (1.3)	1	1.0
30-<35	1 (0.6)	1	0.5	1 (0.7)	1	0.6	0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Pancytopenia									
<30	0			0			0		
30-<35	0			1 (0.7)	1	0.6	0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hypochromic anaemia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1	(1.4)	1 1.0	0			0		
Microcytic anaemia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1	(1.4)	1 1.0	0			0		
Normocytic anaemia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			0			0		
Platelet disorders									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Thrombocytosis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Spleen, lymphatic and reticuloendothelial system disorders									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			1 (0.7)	1	0.6	0		
35-<40	0			0			0		
>=40	0			0			2 (2.2)	2	1.6
Splenomegaly									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			1 (0.7)	1	0.6	0		
35-<40	0			0			0		
>=40	0			0			0		
Lymphadenopathy									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			2 (2.2)	2	1.6
White blood cell disorders									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6
35-<40	1 (1.0)	1	0.8	0			1 (1.0)	1	0.8
>=40	0			0			0		
Leukocytosis									
<30	0			0			0		
30-<35	0			0			1 (0.7)	1	0.6
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lymphopenia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Hepatobiliary disorders									
<30	0			2 (2.9)	2	2.2	3 (3.9)	6	6.1
30-<35	5 (3.1)	5	2.3	5 (3.6)	6	3.4	1 (0.7)	1	0.6
35-<40	5 (5.1)	6	4.6	2 (1.9)	2	1.4	3 (3.1)	4	3.1
>=40	0			1 (1.1)	3	2.4	2 (2.2)	3	2.5
Hepatic and hepatobiliary disorders									
<30	0			1 (1.5)	1	1.1	3 (3.9)	4	4.1
30-<35	3 (1.8)	3	1.4	4 (2.9)	5	2.8	1 (0.7)	1	0.6
35-<40	3 (3.0)	3	2.3	2 (1.9)	2	1.4	3 (3.1)	3	2.3
>=40	0			1 (1.1)	1	0.8	2 (2.2)	2	1.6
Hepatic steatosis									
<30	0			0			1 (1.3)	1	1.0
30-<35	2 (1.2)	2	0.9	2 (1.4)	2	1.1	1 (0.7)	1	0.6
35-<40	1 (1.0)	1	0.8	1 (1.0)	1	0.7	2 (2.1)	2	1.5
>=40	0			1 (1.1)	1	0.8	1 (1.1)	1	0.8
Hepatic cyst									
<30	0			1 (1.5)	1	1.1	0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Portal vein thrombosis									
<30	0			0			1	(1.3)	1 1.0
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Hepatic lesion									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	0			0			0		
>=40	0			0			0		
Non-alcoholic steatohepatitis									
<30	0			0			0		
30-<35	0			1	(0.7)	1 0.6	0		
35-<40	0			0			0		
>=40	0			0			0		
Nonalcoholic fatty liver disease									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	1	(0.7)	1 0.6	0		
35-<40	0			0			0		
>=40	0			0			0		
Drug-induced liver injury									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Hepatic cirrhosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hepatomegaly									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Liver disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Portal hypertension									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Gallbladder disorders									
<30	0			1 (1.5)	1	1.1	1 (1.3)	2	2.0
30-<35	2 (1.2)	2	0.9	1 (0.7)	1	0.6	0		
35-<40	2 (2.0)	3	2.3	0			1 (1.0)	1	0.8
>=40	0			1 (1.1)	2	1.6	1 (1.1)	1	0.8
Gallbladder polyp									
<30	0			1 (1.5)	1	1.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	1 (0.6)	1	0.5	1 (0.7)	1	0.6	0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Cholecystitis chronic									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Cholelithiasis									
<30	0			0			1 (1.3)	1	1.0
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	2 (2.0)	2	1.5	0			1 (1.0)	1	0.8
>=40	0			1 (1.1)	1	0.8	1 (1.1)	1	0.8
Cholecystitis acute									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
<30	3 (4.5)	3	3.6	0			2 (2.6)	2	2.0
30-<35	7 (4.3)	8	3.7	1 (0.7)	1	0.6	3 (2.2)	4	2.2
35-<40	2 (2.0)	4	3.1	4 (3.9)	5	3.6	3 (3.1)	4	3.1
>=40	1 (1.4)	1	1.0	4 (4.3)	4	3.2	4 (4.3)	4	3.3
Gastrointestinal neoplasms benign									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	1 (1.5)	1	1.2	0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	1 (1.0)	2	1.5	1 (1.0)	1	0.7	0		
>=40	0			1 (1.1)	1	0.8	2 (2.2)	2	1.6
Gastrointestinal tract adenoma									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Benign duodenal neoplasm									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Colon adenoma									
<30	1 (1.5)	1	1.2	0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	1 (1.0)	2	1.5	0			0		
>=40	0			0			2 (2.2)	2	1.6
Leukaemias									
<30	0			0			0		
30-<35	0			1 (0.7)	1	0.6	0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Chronic lymphocytic leukaemia									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Myeloid leukaemia									
<30	0			0			0		
30-<35	0			1 (0.7)	1	0.6	0		
35-<40	0			0			0		
>=40	0			0			0		
Cutaneous neoplasms benign									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			1 (1.1)	1	0.8	0		
Anogenital warts									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			1 (1.1)	1	0.8	0		
Melanocytic naevus									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		
Soft tissue neoplasms benign									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
35-<40	0				0				0			
>=40	0				1	(1.1)	1	0.8	1	(1.1)	1	0.8
Lipoma												
<30	0				0				0			
30-<35	1	(0.6)	1	0.5	0				0			
35-<40	0				0				0			
>=40	0				1	(1.1)	1	0.8	1	(1.1)	1	0.8
Lymphomas non-Hodgkin's unspecified histology												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				1	(1.0)	1	0.7	0			
>=40	0				0				0			
Gastrointestinal lymphoma												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				1	(1.0)	1	0.7	0			
>=40	0				0				0			
Miscellaneous and site unspecified neoplasms malignant and unspecified												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				1	(1.0)	1	0.7	0			
>=40	0				0				0			
Squamous cell carcinoma												
<30	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	1 (1.0)	1	0.8
>=40	0			0			0		
Nasal cavity cancer									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Keratinising squamous cell carcinoma of nasopharynx									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			0		
Skeletal neoplasms benign									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		
>=40	0			0			0		
Osteochondroma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Breast neoplasms malignant and unspecified (incl nipple)									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Invasive ductal breast carcinoma									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Endocrine neoplasms benign									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			0			0		
Pituitary tumour benign									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(1.0)	1 0.8
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Endocrine neoplasms malignant and unspecified												
<30	0				0				0			
30-<35	1	(0.6)	1	0.5	0				0			
35-<40	0				0				0			
>=40	0				0				0			
Neuroendocrine tumour												
<30	0				0				0			
30-<35	1	(0.6)	1	0.5	0				0			
35-<40	0				0				0			
>=40	0				0				0			
Gastrointestinal neoplasms malignant and unspecified												
<30	1	(1.5)	1	1.2	0				1	(1.3)	1	1.0
30-<35	2	(1.2)	2	0.9	0				1	(0.7)	1	0.6
35-<40	2	(2.0)	2	1.5	0				0			
>=40	0				0				0			
Adenocarcinoma gastric												
<30	0				0				0			
30-<35	0				0				0			
35-<40	1	(1.0)	1	0.8	0				0			
>=40	0				0				0			
Adenocarcinoma of colon												
<30	0				0				0			
30-<35	0				0				0			
35-<40	1	(1.0)	1	0.8	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>=40	0			0			0		
Gastric cancer									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Gastric cancer stage IV									
<30	0			0			1	(1.3)	1 1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal stromal tumour									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal submucosal tumour									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Oral neoplasm									
<30	1	(1.5)	1 1.2	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hepatobiliary neoplasms malignant and unspecified									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hepatocellular carcinoma									
<30	0			0			1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Metastases									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Metastases to liver									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Reproductive neoplasms female benign									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1 (1.4)	1	1.0	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Uterine leiomyoma									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1	(1.4)	1 1.0	0			0		
Reproductive neoplasms female malignant and unspecified									
<30	1	(1.5)	1 1.2	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Uterine cancer									
<30	1	(1.5)	1 1.2	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Reproductive neoplasms male malignant and unspecified									
<30	0			0			0		
30-<35	0			0			3	(2.2)	3 1.7
35-<40	0			0			0		
>=40	0			0			0		
Prostate cancer									
<30	0			0			0		
30-<35	0			0			3	(2.2)	3 1.7
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Skin neoplasms malignant and unspecified									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			1 (1.1)	1	0.8
Basal cell carcinoma									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (1.0)	1	0.8
>=40	0			0			1 (1.1)	1	0.8
Immune system disorders									
<30	2 (3.0)	2	2.4	2 (2.9)	2	2.2	2 (2.6)	3	3.1
30-<35	1 (0.6)	1	0.5	1 (0.7)	1	0.6	2 (1.5)	2	1.1
35-<40	2 (2.0)	2	1.5	1 (1.0)	1	0.7	1 (1.0)	1	0.8
>=40	1 (1.4)	1	1.0	2 (2.2)	2	1.6	1 (1.1)	1	0.8
Allergic conditions									
<30	2 (3.0)	2	2.4	2 (2.9)	2	2.2	2 (2.6)	3	3.1
30-<35	0			1 (0.7)	1	0.6	2 (1.5)	2	1.1
35-<40	2 (2.0)	2	1.5	1 (1.0)	1	0.7	1 (1.0)	1	0.8
>=40	1 (1.4)	1	1.0	2 (2.2)	2	1.6	1 (1.1)	1	0.8
Seasonal allergy									
<30	1 (1.5)	1	1.2	1 (1.5)	1	1.1	1 (1.3)	2	2.0
30-<35	0			1 (0.7)	1	0.6	2 (1.5)	2	1.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			1 (1.0)	1	0.7	1 (1.0)	1	0.8
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	0		
Allergy to arthropod sting									
<30	0			1 (1.5)	1	1.1	1 (1.3)	1	1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hypersensitivity									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			1 (1.1)	1	0.8	0		
Allergy to chemicals									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Drug hypersensitivity									
<30	1 (1.5)	1	1.2	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Multiple allergies									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			1 (1.1)	1	0.8
Immune disorders NEC									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Immunisation reaction									
<30	0			0			0		
30-<35	1 (0.6)	1	0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Endocrine disorders									
<30	1 (1.5)	1	1.2	1 (1.5)	1	1.1	1 (1.3)	1	1.0
30-<35	1 (0.6)	1	0.5	0			1 (0.7)	1	0.6
35-<40	0			2 (1.9)	2	1.4	0		
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	2 (2.2)	2	1.6
Thyroid gland disorders									
<30	1 (1.5)	1	1.2	1 (1.5)	1	1.1	1 (1.3)	1	1.0
30-<35	1 (0.6)	1	0.5	0			1 (0.7)	1	0.6
35-<40	0			2 (1.9)	2	1.4	0		
>=40	1 (1.4)	1	1.0	1 (1.1)	1	0.8	2 (2.2)	2	1.6
Hypothyroidism									
<30	1 (1.5)	1	1.2	0			0		
30-<35	0			0			0		
35-<40	0			1 (1.0)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>=40	0			1	(1.1)	1 0.8	0		
Thyroid cyst									
<30	0			1	(1.5)	1 1.1	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Primary hyperthyroidism									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(1.0)	1 0.7	0		
>=40	0			0			0		
Autoimmune thyroiditis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1	(1.4)	1 1.0	0			1	(1.1)	1 0.8
Goitre									
<30	0			0			1	(1.3)	1 1.0
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Silent thyroiditis									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Thyroid mass									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Surgical and medical procedures									
<30	0			1	(1.5)	1 1.1	0		
30-<35	1	(0.6)	1 0.5	0			2	(1.5)	2 1.1
35-<40	1	(1.0)	1 0.8	0			0		
>=40	1	(1.4)	1 1.0	0			3	(3.2)	4 3.3
Endocrine gland therapeutic procedures									
<30	0			1	(1.5)	1 1.1	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Thyroidectomy									
<30	0			1	(1.5)	1 1.1	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Bone and joint therapeutic procedures									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	0			0			1	(1.1)	1 0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bone graft									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (1.0)	1	0.8	0			0		
>=40	0			0			0		
Joint injection									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (1.1)	1	0.8
Cardiac therapeutic procedures									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1 (1.4)	1	1.0	0			0		
Cardiac pacemaker replacement									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1 (1.4)	1	1.0	0			0		
Eye therapeutic procedures									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (1.1)	1	0.8
Cataract operation									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Head and neck therapeutic procedures									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Tooth extraction									
<30	0			0			0		
30-<35	1	(0.6)	1 0.5	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Male genital tract therapeutic procedures									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Sperm aspiration									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Therapeutic procedures and supportive care NEC									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			2	(2.2)	2 1.6
Cyst removal									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Nerve block									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(1.1)	1 0.8
Stent placement									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Congenital, familial and genetic disorders									
<30	0			0			0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
35-<40	1	(1.0)	1 0.8	0			2	(2.1)	2 1.5
>=40	0			0			0		
Reproductive tract and breast disorders congenital									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			2	(2.1)	2 1.5
>=40	0			0			0		
Phimosis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			2	(2.1)	2 1.5
>=40	0			0			0		
Respiratory disorders congenital									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	0			0			0		
Laryngeal web									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	0			0			0		
Pregnancy, puerperium and perinatal conditions									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Abortions and stillbirth									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Abortion spontaneous									
<30	0			0			0		
30-<35	0			0			1	(0.7)	1 0.6
35-<40	0			0			0		
>=40	0			0			0		
Social circumstances									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	1	(1.4)	1 1.0	0			0		
Economic and housing issues									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(1.0)	1 0.8	0			0		
>=40	1	(1.4)	1 1.0	0			0		
Stress at work									
<30	0			0			0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
35-<40	1	(1.0)	1	0.8	0				0			
>=40	1	(1.4)	1	1.0	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

23 Adverse events by BMI at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
<30	46		62.5		86		118.2		38		52.0	
30-<35	35		47.7		75		105.8		44		62.7	
35-<40	17		23.1		21		27.2		12		17.1	
>=40	2		2.8		17		23.8		7		10.0	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
<30	36	(78.3)	142	227.1	71	(82.6)	363	307.1	28	(73.7)	86	165.3
30-<35	29	(82.9)	246	515.5	69	(92.0)	307	290.2	35	(79.5)	98	156.2
35-<40	15	(88.2)	80	345.9	16	(76.2)	84	308.8	11	(91.7)	36	210.1
>=40	2	(100)	15	527.8	15	(88.2)	80	335.7	6	(85.7)	15	150.5
Serious												
Yes												
<30	2	(4.3)	2	3.2	4	(4.7)	6	5.1	5	(13.2)	5	9.6
30-<35	5	(14.3)	8	16.8	3	(4.0)	3	2.8	1	(2.3)	1	1.6
35-<40	0				2	(9.5)	2	7.4	0			
>=40	0				1	(5.9)	1	4.2	1	(14.3)	1	10.0
No												
<30	36	(78.3)	140	223.9	71	(82.6)	357	302.1	27	(71.1)	81	155.7
30-<35	29	(82.9)	238	498.8	69	(92.0)	304	287.3	34	(77.3)	97	154.6
35-<40	15	(88.2)	80	345.9	15	(71.4)	82	301.5	11	(91.7)	36	210.1
>=40	2	(100)	15	527.8	15	(88.2)	79	331.5	6	(85.7)	14	140.5

Adverse events with onset prior to randomisation are not included.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by BMI at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severity									
Severe									
<30	1 (2.2)	1	1.6	2 (2.3)	3	2.5	4 (10.5)	4	7.7
30-<35	2 (5.7)	2	4.2	0			1 (2.3)	1	1.6
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Moderate									
<30	5 (10.9)	5	8.0	11 (12.8)	18	15.2	7 (18.4)	9	17.3
30-<35	6 (17.1)	45	94.3	8 (10.7)	14	13.2	2 (4.5)	2	3.2
35-<40	3 (17.6)	13	56.2	4 (19.0)	7	25.7	0		
>=40	0			2 (11.8)	3	12.6	2 (28.6)	2	20.1
Mild									
<30	34 (73.9)	136	217.5	71 (82.6)	342	289.4	25 (65.8)	73	140.4
30-<35	28 (80.0)	199	417.0	67 (89.3)	293	276.9	34 (77.3)	95	151.5
35-<40	15 (88.2)	67	289.7	15 (71.4)	76	279.4	11 (91.7)	36	210.1
>=40	2 (100)	15	527.8	15 (88.2)	77	323.1	6 (85.7)	13	130.4
Relationship to trial product									
Missing									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Probable									
<30	10 (21.7)	17	27.2	24 (27.9)	79	66.8	5 (13.2)	8	15.4
30-<35	7 (20.0)	31	65.0	18 (24.0)	44	41.6	3 (6.8)	3	4.8
35-<40	7 (41.2)	12	51.9	8 (38.1)	20	73.5	2 (16.7)	5	29.2
>=40	1 (50.0)	1	35.2	5 (29.4)	15	62.9	0		

Adverse events with onset prior to randomisation are not included.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by BMI at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Possible									
<30	23 (50.0)	33	52.8	36 (41.9)	82	69.4	4 (10.5)	9	17.3
30-<35	19 (54.3)	131	274.5	32 (42.7)	84	79.4	3 (6.8)	5	8.0
35-<40	11 (64.7)	24	103.8	9 (42.9)	23	84.6	3 (25.0)	3	17.5
>=40	2 (100)	2	70.4	7 (41.2)	17	71.3	0		
Unlikely									
<30	34 (73.9)	92	147.2	66 (76.7)	201	170.1	24 (63.2)	69	132.7
30-<35	27 (77.1)	84	176.0	61 (81.3)	179	169.2	34 (77.3)	90	143.5
35-<40	11 (64.7)	44	190.2	11 (52.4)	41	150.7	10 (83.3)	28	163.4
>=40	1 (50.0)	12	422.3	14 (82.4)	48	201.4	6 (85.7)	15	150.5
Outcome									
Recovered									
<30	34 (73.9)	116	185.5	68 (79.1)	326	275.8	28 (73.7)	77	148.0
30-<35	28 (80.0)	224	469.4	65 (86.7)	268	253.3	31 (70.5)	70	111.6
35-<40	14 (82.4)	58	250.8	16 (76.2)	69	253.7	10 (83.3)	28	163.4
>=40	2 (100)	11	387.1	15 (88.2)	66	277.0	6 (85.7)	11	110.4
Recovering									
<30	1 (2.2)	1	1.6	5 (5.8)	7	5.9	1 (2.6)	1	1.9
30-<35	4 (11.4)	7	14.7	5 (6.7)	6	5.7	2 (4.5)	2	3.2
35-<40	4 (23.5)	8	34.6	2 (9.5)	2	7.4	1 (8.3)	1	5.8
>=40	0			4 (23.5)	6	25.2	1 (14.3)	1	10.0
Not Recovered									
<30	14 (30.4)	25	40.0	21 (24.4)	30	25.4	4 (10.5)	8	15.4
30-<35	14 (40.0)	15	31.4	22 (29.3)	33	31.2	14 (31.8)	26	41.4
35-<40	6 (35.3)	14	60.5	7 (33.3)	13	47.8	5 (41.7)	7	40.9
>=40	1 (50.0)	4	140.8	4 (23.5)	8	33.6	3 (42.9)	3	30.1

Adverse events with onset prior to randomisation are not included.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by BMI at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Leading to												
Permanent treatment discontinuation												
<30	0				4	(4.7)	8	6.8	1	(2.6)	1	1.9
30-<35	2	(5.7)	5	10.5	1	(1.3)	1	0.9	0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			
Temporary interruption of trial product												
<30	2	(4.3)	3	4.8	7	(8.1)	16	13.5	2	(5.3)	2	3.8
30-<35	2	(5.7)	2	4.2	6	(8.0)	8	7.6	2	(4.5)	2	3.2
35-<40	2	(11.8)	3	13.0	0				0			
>=40	1	(50.0)	1	35.2	1	(5.9)	2	8.4	1	(14.3)	1	10.0
Dose reduction of trial product												
<30	0				8	(9.3)	11	9.3	0			
30-<35	2	(5.7)	2	4.2	5	(6.7)	7	6.6	0			
35-<40	1	(5.9)	1	4.3	1	(4.8)	1	3.7	0			
>=40	0				0				0			

Adverse events with onset prior to randomisation are not included.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

24 Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
<30	46		62.5		86		118.2		38		52.0	
30-<35	35		47.7		75		105.8		44		62.7	
35-<40	17		23.1		21		27.2		12		17.1	
>=40	2		2.8		17		23.8		7		10.0	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
<30	36	(78.3)	142	227.1	71	(82.6)	363	307.1	28	(73.7)	86	165.3
30-<35	29	(82.9)	246	515.5	69	(92.0)	307	290.2	35	(79.5)	98	156.2
35-<40	15	(88.2)	80	345.9	16	(76.2)	84	308.8	11	(91.7)	36	210.1
>=40	2	(100)	15	527.8	15	(88.2)	80	335.7	6	(85.7)	15	150.5
Gastrointestinal disorders												
<30	25	(54.3)	48	76.8	49	(57.0)	146	123.5	11	(28.9)	14	26.9
30-<35	22	(62.9)	164	343.7	48	(64.0)	125	118.1	10	(22.7)	15	23.9
35-<40	15	(88.2)	39	168.6	11	(52.4)	39	143.4	7	(58.3)	12	70.0
>=40	2	(100)	5	175.9	10	(58.8)	33	138.5	2	(28.6)	2	20.1
Gastrointestinal motility and defaecation conditions												
<30	17	(37.0)	20	32.0	33	(38.4)	46	38.9	2	(5.3)	2	3.8
30-<35	14	(40.0)	49	102.7	31	(41.3)	49	46.3	3	(6.8)	3	4.8
35-<40	9	(52.9)	14	60.5	6	(28.6)	10	36.8	4	(33.3)	4	23.3
>=40	1	(50.0)	1	35.2	8	(47.1)	14	58.7	0			
Constipation												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	10 (21.7)	11	17.6	22 (25.6)	25	21.2	0		
30-<35	5 (14.3)	6	12.6	21 (28.0)	24	22.7	2 (4.5)	2	3.2
35-<40	3 (17.6)	4	17.3	5 (23.8)	6	22.1	1 (8.3)	1	5.8
>=40	1 (50.0)	1	35.2	4 (23.5)	5	21.0	0		
Diarrhoea									
<30	7 (15.2)	8	12.8	13 (15.1)	18	15.2	2 (5.3)	2	3.8
30-<35	8 (22.9)	41	85.9	12 (16.0)	22	20.8	1 (2.3)	1	1.6
35-<40	7 (41.2)	10	43.2	2 (9.5)	4	14.7	3 (25.0)	3	17.5
>=40	0			5 (29.4)	8	33.6	0		
Gastrooesophageal reflux disease									
<30	1 (2.2)	1	1.6	3 (3.5)	3	2.5	0		
30-<35	1 (2.9)	1	2.1	3 (4.0)	3	2.8	0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal motility disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Irritable bowel syndrome									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal signs and symptoms									
<30	14 (30.4)	19	30.4	30 (34.9)	78	66.0	6 (15.8)	8	15.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	12 (34.3)	107	224.2	27 (36.0)	56	52.9	3 (6.8)	3	4.8
35-<40	11 (64.7)	22	95.1	8 (38.1)	20	73.5	2 (16.7)	6	35.0
>=40	2 (100)	3	105.6	6 (35.3)	15	62.9	0		
Nausea									
<30	6 (13.0)	6	9.6	16 (18.6)	34	28.8	3 (7.9)	3	5.8
30-<35	7 (20.0)	14	29.3	11 (14.7)	18	17.0	1 (2.3)	1	1.6
35-<40	4 (23.5)	5	21.6	5 (23.8)	10	36.8	0		
>=40	1 (50.0)	2	70.4	3 (17.6)	4	16.8	0		
Vomiting									
<30	3 (6.5)	3	4.8	4 (4.7)	10	8.5	1 (2.6)	1	1.9
30-<35	3 (8.6)	27	56.6	9 (12.0)	14	13.2	1 (2.3)	1	1.6
35-<40	4 (23.5)	4	17.3	1 (4.8)	1	3.7	0		
>=40	0			3 (17.6)	4	16.8	0		
Dyspepsia									
<30	0			3 (3.5)	3	2.5	0		
30-<35	3 (8.6)	14	29.3	1 (1.3)	1	0.9	0		
35-<40	3 (17.6)	3	13.0	3 (14.3)	7	25.7	1 (8.3)	4	23.3
>=40	0			2 (11.8)	3	12.6	0		
Abdominal discomfort									
<30	5 (10.9)	6	9.6	7 (8.1)	10	8.5	0		
30-<35	4 (11.4)	4	8.4	3 (4.0)	4	3.8	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Abdominal pain									
<30	0			5 (5.8)	7	5.9	0		
30-<35	2 (5.7)	2	4.2	6 (8.0)	8	7.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	1 (5.9)	2	8.6	1 (4.8)	1	3.7	0		
>=40	0			0			0		
Abdominal pain upper									
<30	0			6 (7.0)	6	5.1	1 (2.6)	1	1.9
30-<35	2 (5.7)	3	6.3	3 (4.0)	6	5.7	0		
35-<40	1 (5.9)	2	8.6	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Abdominal distension									
<30	1 (2.2)	1	1.6	3 (3.5)	4	3.4	2 (5.3)	3	5.8
30-<35	3 (8.6)	4	8.4	3 (4.0)	3	2.8	0		
35-<40	3 (17.6)	3	13.0	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Eructation									
<30	0			1 (1.2)	1	0.8	0		
30-<35	3 (8.6)	20	41.9	0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Faeces soft									
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Abdominal tenderness									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Faeces hard									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Flatulence									
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	18	37.7	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Abdominal pain lower									
<30	1 (2.2)	2	3.2	0			0		
30-<35	0			0			0		
35-<40	0			0			1 (8.3)	2	11.7
>=40	0			0			0		
Epigastric discomfort									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Dental and gingival conditions									
<30	3 (6.5)	3	4.8	4 (4.7)	4	3.4	3 (7.9)	3	5.8
30-<35	3 (8.6)	3	6.3	6 (8.0)	7	6.6	1 (2.3)	1	1.6
35-<40	0			2 (9.5)	2	7.4	1 (8.3)	1	5.8
>=40	0			2 (11.8)	2	8.4	1 (14.3)	1	10.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dental caries									
<30	3 (6.5)	3	4.8	3 (3.5)	3	2.5	3 (7.9)	3	5.8
30-<35	1 (2.9)	1	2.1	4 (5.3)	5	4.7	0		
35-<40	0			2 (9.5)	2	7.4	1 (8.3)	1	5.8
>=40	0			2 (11.8)	2	8.4	1 (14.3)	1	10.0
Toothache									
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Tooth impacted									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Dental cyst									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal conditions NEC									
<30	1 (2.2)	1	1.6	4 (4.7)	6	5.1	0		
30-<35	2 (5.7)	2	4.2	4 (5.3)	4	3.8	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	2 (9.5)	2	7.4	0		
>=40	0			0			0		
Food poisoning									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			0			0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Gastric disorder									
<30	0			2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	0		
>=40	0			0			0		
Gastrointestinal disorder									
<30	1 (2.2)	1	1.6	2 (2.3)	4	3.4	0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Barrett's oesophagus									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal inflammatory conditions									
<30	1 (2.2)	1	1.6	6 (7.0)	7	5.9	0		
30-<35	0			3 (4.0)	3	2.8	4 (9.1)	4	6.4
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			1 (14.3)	1	10.0
Enterocolitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			3 (4.0)	3	2.8	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Chronic gastritis									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Gastritis									
<30	0			3 (3.5)	3	2.5	0		
30-<35	0			0			2 (4.5)	2	3.2
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Colitis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Colitis ischaemic									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Enteritis									
<30	0			1 (1.2)	1	0.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Oral soft tissue conditions									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			2 (9.5)	2	7.4	0		
>=40	0			0			0		
Stomatitis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			2 (9.5)	2	7.4	0		
>=40	0			0			0		
Angular cheilitis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Benign neoplasms gastrointestinal									
<30	2 (4.3)	2	3.2	4 (4.7)	4	3.4	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			1 (4.8)	2	7.4	1 (8.3)	1	5.8
>=40	0			0			0		
Large intestine polyp									
<30	1 (2.2)	1	1.6	3 (3.5)	3	2.5	0		
30-<35	1 (2.9)	1	2.1	0			1 (2.3)	1	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
35-<40	0				1	(4.8)	1	3.7	1	(8.3)	1	5.8
>=40	0				0				0			
Gastric polyps												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				1	(4.8)	1	3.7	0			
>=40	0				0				0			
Rectal polyp												
<30	1	(2.2)	1	1.6	0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Gastrointestinal haemorrhages NEC												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				1	(5.9)	1	4.2	0			
Mallory-Weiss syndrome												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				1	(5.9)	1	4.2	0			
Anal haemorrhage												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Anal and rectal conditions NEC									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Anal fissure									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Gastrointestinal ulceration and perforation									
<30	0			0			0		
30-<35	0			1 (1.3)	2	1.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Erosive duodenitis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Gastritis erosive									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Gastrointestinal vascular conditions									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Haemorrhoids									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Diverticular disorders									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Diverticulum intestinal									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Gastrointestinal stenosis and obstruction									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Intestinal obstruction									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Salivary gland conditions									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Parotid gland enlargement									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Infections and infestations									
<30	18 (39.1)	21	33.6	37 (43.0)	62	52.5	10 (26.3)	15	28.8
30-<35	15 (42.9)	27	56.6	27 (36.0)	57	53.9	18 (40.9)	29	46.2
35-<40	8 (47.1)	11	47.6	7 (33.3)	12	44.1	5 (41.7)	7	40.9
>=40	1 (50.0)	5	175.9	9 (52.9)	22	92.3	2 (28.6)	2	20.1
Infections - pathogen unspecified									
<30	16 (34.8)	18	28.8	33 (38.4)	53	44.8	10 (26.3)	15	28.8
30-<35	14 (40.0)	25	52.4	24 (32.0)	52	49.1	18 (40.9)	28	44.6
35-<40	8 (47.1)	11	47.6	7 (33.3)	11	40.4	4 (33.3)	6	35.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	1 (50.0)	4	140.8	7 (41.2)	16	67.1	2 (28.6)	2	20.1
Nasopharyngitis									
<30	8 (17.4)	9	14.4	22 (25.6)	30	25.4	6 (15.8)	9	17.3
30-<35	12 (34.3)	18	37.7	19 (25.3)	31	29.3	9 (20.5)	11	17.5
35-<40	3 (17.6)	5	21.6	6 (28.6)	8	29.4	3 (25.0)	4	23.3
>=40	1 (50.0)	4	140.8	6 (35.3)	12	50.4	0		
Gastroenteritis									
<30	4 (8.7)	4	6.4	4 (4.7)	6	5.1	0		
30-<35	2 (5.7)	3	6.3	3 (4.0)	3	2.8	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	0		
>=40	0			3 (17.6)	3	12.6	0		
Bronchitis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	2 (5.7)	2	4.2	4 (5.3)	6	5.7	0		
35-<40	1 (5.9)	1	4.3	1 (4.8)	2	7.4	0		
>=40	0			0			0		
Sinusitis									
<30	0			0			0		
30-<35	0			0			2 (4.5)	2	3.2
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			1 (5.9)	1	4.2	1 (14.3)	1	10.0
Cystitis									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pharyngitis									
<30	2 (4.3)	2	3.2	2 (2.3)	2	1.7	2 (5.3)	3	5.8
30-<35	0			1 (1.3)	2	1.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			1 (14.3)	1	10.0
Conjunctivitis									
<30	0			1 (1.2)	2	1.7	1 (2.6)	1	1.9
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Rhinitis									
<30	0			2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	0			1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Tonsillitis									
<30	0			2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	0			3 (6.8)	4	6.4
35-<40	0			0			0		
>=40	0			0			0		
Diverticulitis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Folliculitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			0			0		
30-<35	0			1 (1.3)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Gingivitis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Hordeolum									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Urinary tract infection									
<30	0			0			0		
30-<35	0			1 (1.3)	3	2.8	0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Acute sinusitis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Enteritis infectious									
<30	0			1 (1.2)	1	0.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Pelvic inflammatory disease									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Pyelonephritis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Pyelonephritis acute									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Urethritis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Periodontitis									
<30	1 (2.2)	1	1.6	0			1 (2.6)	1	1.9
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
Pyoderma									
<30	0			0			0		
30-<35	0			0			1 (2.3)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		
Upper respiratory tract infection									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			1 (2.3)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		
Vaginal infection									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Viral infectious disorders									
<30	2 (4.3)	2	3.2	5 (5.8)	6	5.1	0		
30-<35	2 (5.7)	2	4.2	4 (5.3)	4	3.8	0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	1 (50.0)	1	35.2	4 (23.5)	4	16.8	0		
Influenza									
<30	1 (2.2)	1	1.6	4 (4.7)	4	3.4	0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			1 (8.3)	1	5.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			2 (11.8)	2	8.4	0		
Herpes zoster									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			2 (11.8)	2	8.4	0		
Gastroenteritis viral									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	0			0		
Herpes simplex									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Infectious mononucleosis									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Bacterial infectious disorders									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			1 (5.9)	2	8.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Erysipelas									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1	(5.9)	2 8.4	0		
Cellulitis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(4.8)	1 3.7	0		
>=40	0			0			0		
Furuncle									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Alpha haemolytic streptococcal infection									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Helicobacter infection									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Fungal infectious disorders									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Tinea pedis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Vulvovaginal candidiasis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Musculoskeletal and connective tissue disorders									
<30	12 (26.1)	14	22.4	21 (24.4)	24	20.3	8 (21.1)	14	26.9
30-<35	6 (17.1)	7	14.7	13 (17.3)	19	18.0	11 (25.0)	14	22.3
35-<40	5 (29.4)	12	51.9	5 (23.8)	5	18.4	2 (16.7)	2	11.7
>=40	1 (50.0)	1	35.2	4 (23.5)	4	16.8	3 (42.9)	4	40.1
Musculoskeletal and connective tissue disorders NEC									
<30	6 (13.0)	6	9.6	13 (15.1)	13	11.0	4 (10.5)	5	9.6
30-<35	1 (2.9)	1	2.1	5 (6.7)	6	5.7	7 (15.9)	8	12.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	3 (17.6)	7	30.3	2 (9.5)	2	7.4	1 (8.3)	1	5.8
>=40	0			2 (11.8)	2	8.4	1 (14.3)	1	10.0
Back pain									
<30	4 (8.7)	4	6.4	11 (12.8)	11	9.3	4 (10.5)	5	9.6
30-<35	1 (2.9)	1	2.1	5 (6.7)	6	5.7	4 (9.1)	5	8.0
35-<40	3 (17.6)	7	30.3	2 (9.5)	2	7.4	0		
>=40	0			1 (5.9)	1	4.2	1 (14.3)	1	10.0
Neck pain									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Musculoskeletal discomfort									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Pain in extremity									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Musculoskeletal pain									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>=40	0				0				0			
Musculoskeletal stiffness												
<30	1	(2.2)	1	1.6	0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Joint disorders												
<30	7	(15.2)	7	11.2	4	(4.7)	4	3.4	4	(10.5)	8	15.4
30-<35	4	(11.4)	5	10.5	4	(5.3)	4	3.8	3	(6.8)	4	6.4
35-<40	4	(23.5)	5	21.6	3	(14.3)	3	11.0	1	(8.3)	1	5.8
>=40	0				2	(11.8)	2	8.4	3	(42.9)	3	30.1
Arthralgia												
<30	5	(10.9)	5	8.0	1	(1.2)	1	0.8	2	(5.3)	4	7.7
30-<35	2	(5.7)	2	4.2	2	(2.7)	2	1.9	2	(4.5)	3	4.8
35-<40	2	(11.8)	3	13.0	2	(9.5)	2	7.4	1	(8.3)	1	5.8
>=40	0				0				1	(14.3)	1	10.0
Periarthritis												
<30	1	(2.2)	1	1.6	2	(2.3)	2	1.7	1	(2.6)	1	1.9
30-<35	1	(2.9)	1	2.1	1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				1	(5.9)	1	4.2	0			
Osteoarthritis												
<30	0				1	(1.2)	1	0.8	0			
30-<35	2	(5.7)	2	4.2	0				1	(2.3)	1	1.6
35-<40	0				1	(4.8)	1	3.7	0			
>=40	0				0				1	(14.3)	1	10.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Rotator cuff syndrome									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Spinal osteoarthritis									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Arthritis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Articular calcification									
<30	0			0			1 (2.6)	2	3.8
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Muscle disorders									
<30	0			4 (4.7)	4	3.4	0		
30-<35	0			5 (6.7)	5	4.7	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	0			0		
Myalgia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
<30	0				3	(3.5)	3	2.5	0			
30-<35	0				1	(1.3)	1	0.9	1	(2.3)	1	1.6
35-<40	0				0				0			
>=40	1	(50.0)	1	35.2	0				0			
Muscle spasms												
<30	0				0				0			
30-<35	0				3	(4.0)	3	2.8	0			
35-<40	0				0				0			
>=40	0				0				0			
Rhabdomyolysis												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Fibromyalgia												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Tendon, ligament and cartilage disorders												
<30	0				1	(1.2)	1	0.8	0			
30-<35	1	(2.9)	1	2.1	2	(2.7)	3	2.8	0			
35-<40	0				0				0			
>=40	0				0				0			
Tendonitis												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Trigger finger									
<30	0			0			0		
30-<35	0			1 (1.3)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Spinal stenosis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Intervertebral disc protrusion									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Synovial and bursal disorders									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Bursitis									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Synovitis									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Skin and subcutaneous tissue disorders									
<30	7 (15.2)	12	19.2	7 (8.1)	8	6.8	4 (10.5)	4	7.7
30-<35	3 (8.6)	6	12.6	10 (13.3)	13	12.3	5 (11.4)	6	9.6
35-<40	2 (11.8)	2	8.6	3 (14.3)	3	11.0	1 (8.3)	3	17.5
>=40	1 (50.0)	2	70.4	4 (23.5)	6	25.2	1 (14.3)	1	10.0
Epidermal and dermal conditions									
<30	6 (13.0)	8	12.8	5 (5.8)	5	4.2	4 (10.5)	4	7.7
30-<35	2 (5.7)	3	6.3	6 (8.0)	7	6.6	2 (4.5)	3	4.8
35-<40	2 (11.8)	2	8.6	2 (9.5)	2	7.4	1 (8.3)	2	11.7
>=40	0			4 (23.5)	5	21.0	1 (14.3)	1	10.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pruritus									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	1 (2.3)	2	3.2
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Dermatitis									
<30	0			0			0		
30-<35	0			1 (1.3)	2	1.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Dermatitis atopic									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	2	8.4	0		
Dyshidrotic eczema									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Rash									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Eczema									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	3 (6.5)	3	4.8	1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			3 (4.0)	3	2.8	0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			1 (14.3)	1	10.0
Stasis dermatitis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Eczema asteatotic									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Dermatitis contact									
<30	0			0			2 (5.3)	2	3.8
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Erythema									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Drug eruption									
<30	1 (2.2)	1	1.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Dry skin									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Pain of skin									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Rash pruritic									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Seborrhoeic dermatitis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1	(8.3)	1 5.8
>=40	0			0			0		
Xanthelasma									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
Skin appendage conditions									
<30	2 (4.3)	2	3.2	1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	5 (6.7)	5	4.7	1 (2.3)	1	1.6
35-<40	0			1 (4.8)	1	3.7	1 (8.3)	1	5.8
>=40	1 (50.0)	1	35.2	0			0		
Alopecia									
<30	1 (2.2)	1	1.6	0			0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Alopecia areata									
<30	0			0			0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Ingrowing nail									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Miliaria									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	1 (50.0)	1	35.2	0			0		
Acne									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Cornification and dystrophic skin disorders									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Hyperkeratosis									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Xeroderma									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Angioedema and urticaria									
<30	1 (2.2)	2	3.2	2 (2.3)	2	1.7	0		
30-<35	2 (5.7)	2	4.2	0			2 (4.5)	2	3.2
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Urticaria									
<30	1 (2.2)	2	3.2	2 (2.3)	2	1.7	0		
30-<35	2 (5.7)	2	4.2	0			2 (4.5)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		
Nervous system disorders									
<30	4 (8.7)	6	9.6	18 (20.9)	29	24.5	2 (5.3)	2	3.8
30-<35	1 (2.9)	1	2.1	13 (17.3)	18	17.0	3 (6.8)	3	4.8
35-<40	2 (11.8)	3	13.0	3 (14.3)	4	14.7	1 (8.3)	1	5.8
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Neurological disorders NEC									
<30	4 (8.7)	6	9.6	12 (14.0)	19	16.1	2 (5.3)	2	3.8
30-<35	0			9 (12.0)	13	12.3	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	0		
>=40	1 (50.0)	1	35.2	0			0		
Dizziness									
<30	3 (6.5)	5	8.0	6 (7.0)	10	8.5	0		
30-<35	0			7 (9.3)	8	7.6	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Hypoaesthesia									
<30	0			2 (2.3)	3	2.5	0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	1 (5.9)	1	4.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	1 (50.0)	1	35.2	0			0		
Dizziness postural									
<30	0			0			0		
30-<35	0			1 (1.3)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Neurological symptom									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Paraesthesia									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Dysaesthesia									
<30	0			1 (1.2)	2	1.7	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Dysgeusia									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Neuralgia									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Somnolence									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Taste disorder									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Intercostal neuralgia									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Sensory loss									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Headaches									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			7 (8.1)	8	6.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	2 (4.5)	2	3.2
35-<40	1 (5.9)	1	4.3	1 (4.8)	2	7.4	1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	0		
Headache									
<30	0			7 (8.1)	8	6.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	2 (4.5)	2	3.2
35-<40	1 (5.9)	1	4.3	1 (4.8)	2	7.4	1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	0		
Peripheral neuropathies									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Carpal tunnel syndrome									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Spinal cord and nerve root disorders									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Sciatica									
<30	0			1 (1.2)	1	0.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
30-<35	0				2	(2.7)	2	1.9	0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			
Central nervous system vascular disorders												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Lacunar infarction												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Cranial nerve disorders (excl neoplasms)												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Parosmia												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Neuromuscular disorders												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Autonomic nervous system imbalance									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Metabolism and nutrition disorders									
<30	3 (6.5)	3	4.8	7 (8.1)	8	6.8	2 (5.3)	2	3.8
30-<35	3 (8.6)	3	6.3	10 (13.3)	10	9.5	4 (9.1)	6	9.6
35-<40	0			3 (14.3)	3	11.0	2 (16.7)	3	17.5
>=40	0			3 (17.6)	3	12.6	0		
Appetite and general nutritional disorders									
<30	3 (6.5)	3	4.8	4 (4.7)	4	3.4	0		
30-<35	2 (5.7)	2	4.2	5 (6.7)	5	4.7	0		
35-<40	0			3 (14.3)	3	11.0	0		
>=40	0			1 (5.9)	1	4.2	0		
Decreased appetite									
<30	3 (6.5)	3	4.8	4 (4.7)	4	3.4	0		
30-<35	2 (5.7)	2	4.2	5 (6.7)	5	4.7	0		
35-<40	0			3 (14.3)	3	11.0	0		
>=40	0			1 (5.9)	1	4.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Purine and pyrimidine metabolism disorders									
<30	0			0			1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	3 (4.0)	3	2.8	2 (4.5)	2	3.2
35-<40	0			0			1 (8.3)	2	11.7
>=40	0			1 (5.9)	1	4.2	0		
Hyperuricaemia									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			1 (1.3)	1	0.9	2 (4.5)	2	3.2
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Gout									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			1 (8.3)	2	11.7
>=40	0			0			0		
Lipid metabolism disorders									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	0		
Dyslipidaemia									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Glucose metabolism disorders (incl diabetes mellitus)												
<30	0				1	(1.2)	2	1.7	1	(2.6)	1	1.9
30-<35	0				1	(1.3)	1	0.9	2	(4.5)	3	4.8
35-<40	0				0				0			
>=40	0				0				0			
Diabetes mellitus												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Type 2 diabetes mellitus												
<30	0				1	(1.2)	2	1.7	0			
30-<35	0				0				1	(2.3)	1	1.6
35-<40	0				0				0			
>=40	0				0				0			
Glucose tolerance impaired												
<30	0				0				0			
30-<35	0				0				1	(2.3)	2	3.2
35-<40	0				0				0			
>=40	0				0				0			
Electrolyte and fluid balance conditions												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Dehydration									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Metabolism disorders NEC									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hypercreatininaemia									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Respiratory, thoracic and mediastinal disorders									
<30	5 (10.9)	7	11.2	11 (12.8)	13	11.0	7 (18.4)	9	17.3
30-<35	4 (11.4)	5	10.5	9 (12.0)	10	9.5	4 (9.1)	7	11.2
35-<40	1 (5.9)	1	4.3	2 (9.5)	2	7.4	1 (8.3)	2	11.7
>=40	0			2 (11.8)	2	8.4	1 (14.3)	1	10.0
Respiratory tract signs and symptoms									
<30	3 (6.5)	4	6.4	9 (10.5)	11	9.3	5 (13.2)	6	11.5
30-<35	3 (8.6)	3	6.3	5 (6.7)	5	4.7	4 (9.1)	7	11.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			1 (4.8)	1	3.7	1 (8.3)	1	5.8
>=40	0			0			1 (14.3)	1	10.0
Upper respiratory tract inflammation									
<30	2 (4.3)	3	4.8	6 (7.0)	8	6.8	3 (7.9)	4	7.7
30-<35	3 (8.6)	3	6.3	4 (5.3)	4	3.8	4 (9.1)	7	11.2
35-<40	0			1 (4.8)	1	3.7	1 (8.3)	1	5.8
>=40	0			0			1 (14.3)	1	10.0
Oropharyngeal pain									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	2 (5.3)	2	3.8
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hiccups									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Rhinorrhoea									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Upper respiratory tract disorders (excl infections)									
<30	2 (4.3)	2	3.2	2 (2.3)	2	1.7	1 (2.6)	2	3.8
30-<35	0			4 (5.3)	4	3.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Rhinitis allergic									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	1 (2.6)	2	3.8
30-<35	0			3 (4.0)	3	2.8	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Epistaxis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Vasomotor rhinitis									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Respiratory disorders NEC									
<30	1 (2.2)	1	1.6	0			1 (2.6)	1	1.9
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Cough									
<30	1 (2.2)	1	1.6	0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			1 (5.9)	1	4.2	0		
Dyspnoea									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Bronchial disorders (excl neoplasms)									
<30	0			0			0		
30-<35	2 (5.7)	2	4.2	0			0		
35-<40	1 (5.9)	1	4.3	0			1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	0		
Asthma									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Cough variant asthma									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	1 (5.9)	1	4.3	0			1 (8.3)	1	5.8
>=40	0			0			0		
Injury, poisoning and procedural complications									
<30	7 (15.2)	7	11.2	12 (14.0)	12	10.2	5 (13.2)	6	11.5
30-<35	6 (17.1)	10	21.0	10 (13.3)	11	10.4	4 (9.1)	4	6.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	2 (11.8)	2	8.6	1 (4.8)	1	3.7	1 (8.3)	1	5.8
>=40	0			2 (11.8)	2	8.4	2 (28.6)	3	30.1
Injuries NEC									
<30	3 (6.5)	3	4.8	9 (10.5)	9	7.6	5 (13.2)	6	11.5
30-<35	3 (8.6)	7	14.7	7 (9.3)	8	7.6	2 (4.5)	2	3.2
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	1 (14.3)	1	10.0
Ligament sprain									
<30	1 (2.2)	1	1.6	0			2 (5.3)	2	3.8
30-<35	2 (5.7)	3	6.3	2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Contusion									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Arthropod sting									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Tendon rupture									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>=40	0			0			0		
Arthropod bite									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Post-traumatic neck syndrome									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			1	(1.3)	1 0.9	1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		
Epicondylitis									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Limb injury									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Subcutaneous haematoma									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tooth fracture									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Limb crushing injury									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Muscle contusion									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Muscle strain									
<30	0			0			0		
30-<35	1 (2.9)	2	4.2	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Road traffic accident									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Skin laceration									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Subdural haematoma									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Bone and joint injuries									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	2 (5.7)	2	4.2	1 (1.3)	1	0.9	0		
35-<40	2 (11.8)	2	8.6	1 (4.8)	1	3.7	0		
>=40	0			1 (5.9)	1	4.2	1 (14.3)	1	10.0
Rib fracture									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Radius fracture									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			1 (14.3)	1	10.0
Ankle fracture									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Meniscus injury									
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Fracture									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Joint injury									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Injuries by physical agents									
<30	3 (6.5)	3	4.8	1 (1.2)	1	0.8	0		
30-<35	0			1 (1.3)	1	0.9	2 (4.5)	2	3.2
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Heat stroke									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			1 (1.3)	1	0.9	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
Thermal burn									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Heat illness									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			2 (4.5)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		
Medication errors and other product use errors and issues									
<30	0			1 (1.2)	1	0.8	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Product administration error									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Accidental overdose									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
General disorders and administration site conditions									
<30	2 (4.3)	4	6.4	7 (8.1)	20	16.9	1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	4 (5.3)	6	5.7	0		
35-<40	0			3 (14.3)	7	25.7	1 (8.3)	1	5.8
>=40	0			2 (11.8)	2	8.4	0		
General system disorders NEC									
<30	2 (4.3)	4	6.4	5 (5.8)	7	5.9	1 (2.6)	1	1.9
30-<35	0			3 (4.0)	5	4.7	0		
35-<40	0			3 (14.3)	6	22.1	0		
>=40	0			0			0		
Malaise									
<30	1 (2.2)	1	1.6	2 (2.3)	3	2.5	0		
30-<35	0			1 (1.3)	2	1.9	0		
35-<40	0			2 (9.5)	3	11.0	0		
>=40	0			0			0		
Fatigue									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Feeling abnormal									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				1	(4.8)	1	3.7	0			
>=40	0				0				0			
Thirst												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				1	(4.8)	1	3.7	0			
>=40	0				0				0			
Non-cardiac chest pain												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Oedema peripheral												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Influenza like illness												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Pain												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
35-<40	0			0			0		
>=40	0			0			0		
Hangover									
<30	1	(2.2)	3 4.8	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hunger									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Body temperature conditions									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			1	(8.3)	1 5.8
>=40	0			2	(11.8)	2 8.4	0		
Pyrexia									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			1	(8.3)	1 5.8
>=40	0			2	(11.8)	2 8.4	0		
Administration site reactions									
<30	0			2	(2.3)	13 11.0	0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			1	(4.8)	1 3.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Injection site erythema									
<30	0			1 (1.2)	12	10.2	0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Injection site dermatitis									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Injection site discomfort									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Investigations									
<30	7 (15.2)	10	16.0	10 (11.6)	12	10.2	5 (13.2)	6	11.5
30-<35	6 (17.1)	6	12.6	3 (4.0)	5	4.7	2 (4.5)	3	4.8
35-<40	0			2 (9.5)	2	7.4	1 (8.3)	1	5.8
>=40	0			1 (5.9)	1	4.2	1 (14.3)	1	10.0
Enzyme investigations NEC									
<30	2 (4.3)	2	3.2	3 (3.5)	4	3.4	2 (5.3)	2	3.8
30-<35	2 (5.7)	2	4.2	2 (2.7)	2	1.9	0		
35-<40	0			1 (4.8)	1	3.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Blood creatine phosphokinase increased									
<30	2 (4.3)	2	3.2	3 (3.5)	4	3.4	2 (5.3)	2	3.8
30-<35	2 (5.7)	2	4.2	2 (2.7)	2	1.9	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Gastrointestinal investigations									
<30	3 (6.5)	3	4.8	2 (2.3)	2	1.7	0		
30-<35	2 (5.7)	2	4.2	1 (1.3)	2	1.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Lipase increased									
<30	2 (4.3)	2	3.2	2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Amylase increased									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Occult blood positive									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Cardiac and vascular investigations (excl enzyme tests)									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Blood pressure decreased									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Electrocardiogram QRS complex prolonged									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Electrocardiogram QT prolonged									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hepatobiliary investigations									
<30	0			1 (1.2)	1	0.8	2 (5.3)	2	3.8
30-<35	0			1 (1.3)	1	0.9	2 (4.5)	2	3.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Aspartate aminotransferase increased									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Liver function test increased									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Alanine aminotransferase increased									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Blood bilirubin increased									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Endocrine investigations (incl sex hormones)									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
Blood thyroid stimulating hormone decreased									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Haematology investigations (incl blood groups)									
<30	1 (2.2)	2	3.2	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Haemoglobin decreased									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Lymphocyte count decreased									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
White blood cell count increased									
<30	1 (2.2)	1	1.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Physical examination and organ system status topics									
<30	0			1	(1.2)	1 0.8	0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Weight decreased									
<30	0			1	(1.2)	1 0.8	0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Lipid analyses									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Blood triglycerides increased									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Metabolic, nutritional and blood gas investigations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		
Blood uric acid increased									
<30	0			0			0		
30-<35	0			0			1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		
Glycosylated haemoglobin increased									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Protein and chemistry analyses NEC									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(14.3)	1 10.0
C-reactive protein increased									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1	(14.3)	1 10.0
Water, electrolyte and mineral investigations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Blood potassium increased									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Eye disorders									
<30	2 (4.3)	3	4.8	10 (11.6)	12	10.2	6 (15.8)	7	13.5
30-<35	3 (8.6)	3	6.3	5 (6.7)	5	4.7	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	2 (9.5)	2	7.4	0		
>=40	0			0			0		
Vision disorders									
<30	0			0			0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			2 (9.5)	2	7.4	0		
>=40	0			0			0		
Optic nerve disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Presbyopia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Amblyopia									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Visual acuity reduced									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Retina, choroid and vitreous haemorrhages and vascular disorders									
<30	1 (2.2)	2	3.2	4 (4.7)	4	3.4	2 (5.3)	2	3.8
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Diabetic retinopathy									
<30	1 (2.2)	2	3.2	3 (3.5)	3	2.5	2 (5.3)	2	3.8
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Retinal exudates									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Retinal haemorrhage									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Retinopathy									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Anterior eye structural change, deposit and degeneration									
<30	0			3	(3.5)	3 2.5	1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Cataract									
<30	0			3	(3.5)	3 2.5	1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ocular infections, irritations and inflammations									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Conjunctivitis allergic									
<30	0			0			1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Ocular hyperaemia									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Glaucoma and ocular hypertension									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Glaucoma									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Open angle glaucoma												
<30	0				0				0			
30-<35	0				0				1	(2.3)	1	1.6
35-<40	0				0				0			
>=40	0				0				0			
Eye disorders NEC												
<30	0				1	(1.2)	2	1.7	1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			
Lacrimal disorder												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Lacrimation increased												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Dry eye												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ocular haemorrhages and vascular disorders NEC									
<30	0			1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Optic disc haemorrhage									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Conjunctival haemorrhage									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Ocular structural change, deposit and degeneration NEC									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Retinal tear									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Macular fibrosis									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Rhegmatogenous retinal detachment									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Reproductive system and breast disorders									
<30	1 (2.2)	1	1.6	5 (5.8)	6	5.1	0		
30-<35	2 (5.7)	3	6.3	2 (2.7)	2	1.9	0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			1 (5.9)	1	4.2	0		
Menstrual cycle and uterine bleeding disorders									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Dysmenorrhoea									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Menstruation irregular									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Menstrual disorder									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Menopause related conditions									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Menopausal symptoms									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Prostatic disorders (excl infections and inflammations)									
<30	1 (2.2)	1	1.6	2 (2.3)	2	1.7	0		
30-<35	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
35-<40	0				0				0			
>=40	0				0				0			
Benign prostatic hyperplasia												
<30	1	(2.2)	1	1.6	2	(2.3)	2	1.7	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Breast disorders												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Breast calcifications												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Male reproductive tract infections and inflammations												
<30	0				1	(1.2)	2	1.7	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Prostatitis												
<30	0				1	(1.2)	2	1.7	0			
30-<35	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
35-<40	0			0			0		
>=40	0			0			0		
Uterine, pelvic and broad ligament disorders									
<30	0			0			0		
30-<35	2	(5.7)	3 6.3	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Endometrial hyperplasia									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Endometriosis									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Uterine haemorrhage									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Vascular disorders									
<30	0			4	(4.7)	4 3.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	1 (2.9)	1	2.1	6 (8.0)	6	5.7	2 (4.5)	2	3.2
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	2 (16.7)	2	11.7
>=40	0			0			0		
Vascular hypertensive disorders									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	2 (16.7)	2	11.7
>=40	0			0			0		
Hypertension									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	2 (16.7)	2	11.7
>=40	0			0			0		
Decreased and nonspecific blood pressure disorders and shock									
<30	0			2 (2.3)	2	1.7	0		
30-<35	0			3 (4.0)	3	2.8	0		
35-<40	0			0			0		
>=40	0			0			0		
Orthostatic hypotension									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Hypotension									
<30	0			1 (1.2)	1	0.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
<30	0			0			0		
30-<35	0			2	(2.7)	2 1.9	1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		
Arteriosclerosis									
<30	0			0			0		
30-<35	0			2	(2.7)	2 1.9	1	(2.3)	1 1.6
35-<40	0			0			0		
>=40	0			0			0		
Embolism and thrombosis									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Venous thrombosis limb									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Renal and urinary disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	2 (5.3)	3	5.8
30-<35	2 (5.7)	2	4.2	3 (4.0)	3	2.8	3 (6.8)	4	6.4
35-<40	1 (5.9)	2	8.6	0			0		
>=40	1 (50.0)	1	35.2	1 (5.9)	1	4.2	0		
Urinary tract signs and symptoms									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	2	8.6	0			0		
>=40	0			1 (5.9)	1	4.2	0		
Hyperuricosuria									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Nocturia									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Proteinuria									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Renal disorders (excl nephropathies)									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	0			2 (2.7)	2	1.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Azotaemia									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Renal cyst									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Urolithiases									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	1 (2.6)	2	3.8
30-<35	2 (5.7)	2	4.2	1 (1.3)	1	0.9	2 (4.5)	3	4.8
35-<40	0			0			0		
>=40	0			0			0		
Ureterolithiasis									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	1 (2.6)	2	3.8
30-<35	0			1 (1.3)	1	0.9	1 (2.3)	2	3.2
35-<40	0			0			0		
>=40	0			0			0		
Calculus urinary									
<30	0			0			0		
30-<35	2 (5.7)	2	4.2	0			1 (2.3)	1	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
35-<40	0				0				0			
>=40	0				0				0			
Nephropathies												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	0				0				0			
>=40	1	(50.0)	1	35.2	0				0			
Diabetic nephropathy												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Nephropathy toxic												
<30	0				0				0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	1	(50.0)	1	35.2	0				0			
Hepatobiliary disorders												
<30	1	(2.2)	1	1.6	2	(2.3)	2	1.7	0			
30-<35	1	(2.9)	1	2.1	2	(2.7)	2	1.9	0			
35-<40	0				0				0			
>=40	0				1	(5.9)	1	4.2	1	(14.3)	1	10.0
Gallbladder disorders												
<30	0				1	(1.2)	1	0.8	0			
30-<35	1	(2.9)	1	2.1	1	(1.3)	1	0.9	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
35-<40	0			0			0		
>=40	0			1	(5.9)	1 4.2	0		
Cholelithiasis									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			1	(5.9)	1 4.2	0		
Gallbladder polyp									
<30	0			1	(1.2)	1 0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hyperplastic cholecystopathy									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Hepatic and hepatobiliary disorders									
<30	1	(2.2)	1 1.6	1	(1.2)	1 0.8	0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			1	(14.3)	1 10.0
Hepatic function abnormal									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Hepatic cyst									
<30	0			1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Alcoholic liver disease									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			1 (14.3)	1	10.0
Hepatic steatosis									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Cardiac disorders									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	1 (2.6)	1	1.9
30-<35	0			2 (2.7)	2	1.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	1 (4.8)	1	3.7	1 (8.3)	1	5.8
>=40	0			0			0		
Coronary artery disorders									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Acute myocardial infarction									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1 (4.8)	1	3.7	0		
>=40	0			0			0		
Cardiac arrhythmias									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			2 (2.7)	2	1.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Tachycardia									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Ventricular extrasystoles									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Arrhythmia									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Atrial fibrillation									
<30	0			0			1 (2.6)	1	1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Cardiac disorders, signs and symptoms NEC									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Palpitations									
<30	1 (2.2)	1	1.6	1 (1.2)	1	0.8	0		
30-<35	0			0			0		
35-<40	0			0			1 (8.3)	1	5.8
>=40	0			0			0		
Psychiatric disorders									
<30	0			2 (2.3)	2	1.7	1 (2.6)	1	1.9
30-<35	2 (5.7)	2	4.2	4 (5.3)	4	3.8	0		
35-<40	2 (11.8)	2	8.6	0			0		
>=40	0			0			0		
Sleep disorders and disturbances									
<30	0			1 (1.2)	1	0.8	0		
30-<35	2 (5.7)	2	4.2	3 (4.0)	3	2.8	0		
35-<40	1 (5.9)	1	4.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>=40	0				0				0			
Insomnia												
<30	0				1	(1.2)	1	0.8	0			
30-<35	2	(5.7)	2	4.2	3	(4.0)	3	2.8	0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			
Depressed mood disorders and disturbances												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Depression												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	0			
35-<40	0				0				0			
>=40	0				0				0			
Mood disorders and disturbances NEC												
<30	0				1	(1.2)	1	0.8	1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Emotional disorder												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>=40	0			0			0		
Listless									
<30	0			0			1	(2.6)	1 1.9
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Adjustment disorders (incl subtypes)									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(5.9)	1 4.3	0			0		
>=40	0			0			0		
Adjustment disorder									
<30	0			0			0		
30-<35	0			0			0		
35-<40	1	(5.9)	1 4.3	0			0		
>=40	0			0			0		
Congenital, familial and genetic disorders									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			1	(4.8)	1 3.7	0		
>=40	0			0			0		
Skin and subcutaneous tissue disorders congenital									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
30-<35	0			0			0		
35-<40	0			1	(4.8)	1 3.7	0		
>=40	0			0			0		
Birth mark									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			1	(4.8)	1 3.7	0		
>=40	0			0			0		
Gastrointestinal tract disorders congenital									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Diverticulitis Meckel's									
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Surgical and medical procedures									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1	(5.9)	1 4.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal therapeutic procedures									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Large intestinal polypectomy									
<30	0			0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			1 (5.9)	1	4.2	0		
Ear and labyrinth disorders									
<30	2 (4.3)	2	3.2	0			0		
30-<35	1 (2.9)	1	2.1	3 (4.0)	3	2.8	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Hearing disorders									
<30	0			0			0		
30-<35	0			2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Deafness									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>=40	0			0			0		
Deafness neurosensory									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Inner ear and VIIIth cranial nerve disorders									
<30	2 (4.3)	2	3.2	0			0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Vertigo									
<30	1 (2.2)	1	1.6	0			0		
30-<35	1 (2.9)	1	2.1	1 (1.3)	1	0.9	1 (2.3)	1	1.6
35-<40	1 (5.9)	1	4.3	0			0		
>=40	0			0			0		
Tinnitus									
<30	1 (2.2)	1	1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Blood and lymphatic system disorders									
<30	0			0			0		
30-<35	2 (5.7)	2	4.2	2 (2.7)	2	1.9	1 (2.3)	1	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
35-<40	0			0			0		
>=40	0			0			0		
Anaemias nonhaemolytic and marrow depression									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Iron deficiency anaemia									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Anaemia									
<30	0			0			0		
30-<35	0			0			1 (2.3)	1	1.6
35-<40	0			0			0		
>=40	0			0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
<30	0			0			0		
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Lymphadenitis									
<30	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
30-<35	1 (2.9)	1	2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
<30	1 (2.2)	1	1.6	0			1 (2.6)	1	1.9
30-<35	1 (2.9)	1	2.1	2 (2.7)	2	1.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Gastrointestinal neoplasms benign									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Intraductal papillary mucinous neoplasm									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Reproductive neoplasms female benign									
<30	0			0			0		
30-<35	0			1 (1.3)	1	0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Uterine leiomyoma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
<30	0			0			0		
30-<35	0			1	(1.3)	1 0.9	0		
35-<40	0			0			0		
>=40	0			0			0		
Hepatobiliary neoplasms malignant and unspecified									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Bile duct adenocarcinoma									
<30	0			0			0		
30-<35	1	(2.9)	1 2.1	0			0		
35-<40	0			0			0		
>=40	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		
Clear cell renal cell carcinoma									
<30	1	(2.2)	1 1.6	0			0		
30-<35	0			0			0		
35-<40	0			0			0		
>=40	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Respiratory and mediastinal neoplasms malignant and unspecified												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Lung neoplasm malignant												
<30	0				0				1	(2.6)	1	1.9
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Immune system disorders												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	1	(2.3)	1	1.6
35-<40	2	(11.8)	2	8.6	0				0			
>=40	0				0				0			
Allergic conditions												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	1	(2.3)	1	1.6
35-<40	2	(11.8)	2	8.6	0				0			
>=40	0				0				0			
Seasonal allergy												
<30	0				0				0			
30-<35	0				1	(1.3)	1	0.9	1	(2.3)	1	1.6
35-<40	1	(5.9)	1	4.3	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by BMI at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>=40	0				0				0			
Food allergy												
<30	0				0				0			
30-<35	0				0				0			
35-<40	1	(5.9)	1	4.3	0				0			
>=40	0				0				0			
Endocrine disorders												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Thyroid gland disorders												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			
Hyperthyroidism												
<30	0				1	(1.2)	1	0.8	0			
30-<35	0				0				0			
35-<40	0				0				0			
>=40	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
BMI: Body mass index (kg/m^2)
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

25 Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
Normal (>=90)	887	1159.8			445	559.3		
Mild RI (60-<90)	401	523.0			200	256.9		
Moderate RI (30-<60)	18	23.2			10	13.4		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Events								
Normal (>=90)	783	(88.3)	6540	563.9	382	(85.8)	2143	383.1
Mild RI (60-<90)	373	(93.0)	2943	562.7	174	(87.0)	1104	429.8
Moderate RI (30-<60)	15	(83.3)	175	753.2	10	(100)	55	411.6
Serious								
Yes								
Normal (>=90)	80	(9.0)	105	9.1	28	(6.3)	30	5.4
Mild RI (60-<90)	42	(10.5)	50	9.6	14	(7.0)	23	9.0
Moderate RI (30-<60)	6	(33.3)	9	38.7	0			
No								
Normal (>=90)	782	(88.2)	6435	554.8	379	(85.2)	2113	377.8
Mild RI (60-<90)	372	(92.8)	2893	553.1	171	(85.5)	1081	420.8
Moderate RI (30-<60)	15	(83.3)	166	714.5	10	(100)	55	411.6
Severity								
Severe								
Normal (>=90)	94	(10.6)	158	13.6	27	(6.1)	39	7.0
Mild RI (60-<90)	43	(10.7)	74	14.1	16	(8.0)	27	10.5
Moderate RI (30-<60)	6	(33.3)	10	43.0	1	(10.0)	2	15.0

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Severity								
Moderate								
Normal (>=90)	472	(53.2)	1643	141.7	204	(45.8)	552	98.7
Mild RI (60-<90)	240	(59.9)	921	176.1	102	(51.0)	299	116.4
Moderate RI (30-<60)	11	(61.1)	48	206.6	5	(50.0)	12	89.8
Mild								
Normal (>=90)	724	(81.6)	4739	408.6	339	(76.2)	1552	277.5
Mild RI (60-<90)	340	(84.8)	1948	372.4	160	(80.0)	778	302.9
Moderate RI (30-<60)	15	(83.3)	117	503.6	8	(80.0)	41	306.8
Relationship to trial product								
Missing								
Normal (>=90)	17	(1.9)	23	2.0	3	(0.7)	3	0.5
Mild RI (60-<90)	6	(1.5)	6	1.1	3	(1.5)	4	1.6
Moderate RI (30-<60)	1	(5.6)	1	4.3	1	(10.0)	1	7.5
Probable								
Normal (>=90)	372	(41.9)	1455	125.4	101	(22.7)	239	42.7
Mild RI (60-<90)	191	(47.6)	676	129.2	41	(20.5)	84	32.7
Moderate RI (30-<60)	8	(44.4)	17	73.2	5	(50.0)	7	52.4
Possible								
Normal (>=90)	488	(55.0)	1865	160.8	147	(33.0)	362	64.7
Mild RI (60-<90)	228	(56.9)	794	151.8	75	(37.5)	188	73.2
Moderate RI (30-<60)	10	(55.6)	41	176.5	1	(10.0)	5	37.4
Unlikely								
Normal (>=90)	692	(78.0)	3197	275.6	357	(80.2)	1539	275.2
Mild RI (60-<90)	325	(81.0)	1467	280.5	170	(85.0)	828	322.3
Moderate RI (30-<60)	15	(83.3)	116	499.3	9	(90.0)	42	314.3

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Recovered								
Normal (>=90)	770	(86.8)	5732	494.2	371	(83.4)	1787	319.5
Mild RI (60-<90)	356	(88.8)	2574	492.1	166	(83.0)	881	343.0
Moderate RI (30-<60)	14	(77.8)	133	572.5	8	(80.0)	42	314.3
Recovering								
Normal (>=90)	35	(3.9)	61	5.3	16	(3.6)	24	4.3
Mild RI (60-<90)	23	(5.7)	27	5.2	9	(4.5)	13	5.1
Moderate RI (30-<60)	1	(5.6)	3	12.9	0			
Recovered With Sequelae								
Normal (>=90)	4	(0.5)	8	0.7	2	(0.4)	2	0.4
Mild RI (60-<90)	6	(1.5)	6	1.1	2	(1.0)	3	1.2
Moderate RI (30-<60)	1	(5.6)	5	21.5	0			
Not Recovered								
Normal (>=90)	344	(38.8)	736	63.5	164	(36.9)	330	59.0
Mild RI (60-<90)	160	(39.9)	336	64.2	93	(46.5)	205	79.8
Moderate RI (30-<60)	9	(50.0)	34	146.3	8	(80.0)	13	97.3
Unknown								
Normal (>=90)	2	(0.2)	3	0.3	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Leading to								
Permanent treatment discontinuation								
Normal (>=90)	57	(6.4)	78	6.7	13	(2.9)	14	2.5
Mild RI (60-<90)	32	(8.0)	42	8.0	7	(3.5)	9	3.5
Moderate RI (30-<60)	3	(16.7)	3	12.9	0			
Temporary interruption of trial product								
Normal (>=90)	83	(9.4)	164	14.1	18	(4.0)	34	6.1
Mild RI (60-<90)	37	(9.2)	86	16.4	8	(4.0)	10	3.9
Moderate RI (30-<60)	6	(33.3)	15	64.6	0			
Dose reduction of trial product								
Normal (>=90)	88	(9.9)	155	13.4	3	(0.7)	7	1.3
Mild RI (60-<90)	34	(8.5)	68	13.0	1	(0.5)	2	0.8
Moderate RI (30-<60)	2	(11.1)	2	8.6	0			

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

26 Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE	
Normal (>=90)	887		1159.8		445		559.3	
Mild RI (60-<90)	401		523.0		200		256.9	
Moderate RI (30-<60)	18		23.2		10		13.4	
Subjects with events	N	(%)	E	R	N	(%)	E	R
Adverse events								
Normal (>=90)	783	(88.3)	6540	563.9	382	(85.8)	2143	383.1
Mild RI (60-<90)	373	(93.0)	2943	562.7	174	(87.0)	1104	429.8
Moderate RI (30-<60)	15	(83.3)	175	753.2	10	(100)	55	411.6
Gastrointestinal disorders								
Normal (>=90)	642	(72.4)	2964	255.6	223	(50.1)	511	91.4
Mild RI (60-<90)	313	(78.1)	1296	247.8	86	(43.0)	219	85.3
Moderate RI (30-<60)	14	(77.8)	49	210.9	5	(50.0)	9	67.3
Gastrointestinal signs and symptoms								
Normal (>=90)	548	(61.8)	1891	163.0	147	(33.0)	284	50.8
Mild RI (60-<90)	264	(65.8)	793	151.6	53	(26.5)	108	42.0
Moderate RI (30-<60)	12	(66.7)	30	129.1	1	(10.0)	3	22.4
Nausea								
Normal (>=90)	381	(43.0)	727	62.7	85	(19.1)	105	18.8
Mild RI (60-<90)	188	(46.9)	328	62.7	28	(14.0)	40	15.6
Moderate RI (30-<60)	8	(44.4)	13	56.0	1	(10.0)	1	7.5
Vomiting								
Normal (>=90)	235	(26.5)	454	39.1	32	(7.2)	38	6.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	86 (21.4)	176	33.7	10 (5.0)	13	5.1
Moderate RI (30-<60)	3 (16.7)	6	25.8	1 (10.0)	1	7.5
Eructation						
Normal (>=90)	76 (8.6)	101	8.7	2 (0.4)	2	0.4
Mild RI (60-<90)	33 (8.2)	35	6.7	1 (0.5)	1	0.4
Moderate RI (30-<60)	3 (16.7)	3	12.9	0		
Abdominal pain						
Normal (>=90)	93 (10.5)	123	10.6	27 (6.1)	32	5.7
Mild RI (60-<90)	36 (9.0)	51	9.8	9 (4.5)	9	3.5
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Abdominal distension						
Normal (>=90)	70 (7.9)	104	9.0	24 (5.4)	34	6.1
Mild RI (60-<90)	24 (6.0)	29	5.5	7 (3.5)	8	3.1
Moderate RI (30-<60)	2 (11.1)	2	8.6	0		
Abdominal pain upper						
Normal (>=90)	90 (10.1)	130	11.2	24 (5.4)	24	4.3
Mild RI (60-<90)	34 (8.5)	45	8.6	11 (5.5)	13	5.1
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dyspepsia						
Normal (>=90)	90 (10.1)	121	10.4	17 (3.8)	21	3.8
Mild RI (60-<90)	45 (11.2)	58	11.1	6 (3.0)	9	3.5
Moderate RI (30-<60)	0			0		
Abdominal discomfort						
Normal (>=90)	31 (3.5)	48	4.1	6 (1.3)	6	1.1
Mild RI (60-<90)	23 (5.7)	29	5.5	3 (1.5)	3	1.2
Moderate RI (30-<60)	2 (11.1)	2	8.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Flatulence						
Normal (>=90)	38 (4.3)	51	4.4	13 (2.9)	14	2.5
Mild RI (60-<90)	27 (6.7)	33	6.3	8 (4.0)	8	3.1
Moderate RI (30-<60)	0			0		
Faeces discoloured						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Retching						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Abdominal pain lower						
Normal (>=90)	10 (1.1)	10	0.9	4 (0.9)	4	0.7
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Faeces soft						
Normal (>=90)	2 (0.2)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Gastrointestinal pain						
Normal (>=90)	2 (0.2)	3	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Regurgitation						
Normal (>=90)	2 (0.2)	3	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Breath odour						
Normal (>=90)	1 (0.1)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Gastrointestinal sounds abnormal						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Epigastric discomfort						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Aerophagia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Faeces hard						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dysphagia						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Abdominal tenderness								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Abnormal faeces								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Oesophageal pain								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Gastrointestinal motility and defaecation conditions								
Normal (>=90)	418	(47.1)	844	72.8	112	(25.2)	160	28.6
Mild RI (60-<90)	200	(49.9)	414	79.2	50	(25.0)	74	28.8
Moderate RI (30-<60)	8	(44.4)	13	56.0	4	(40.0)	5	37.4
Diarrhoea								
Normal (>=90)	291	(32.8)	535	46.1	73	(16.4)	91	16.3
Mild RI (60-<90)	117	(29.2)	226	43.2	30	(15.0)	45	17.5
Moderate RI (30-<60)	4	(22.2)	5	21.5	1	(10.0)	2	15.0
Constipation								
Normal (>=90)	188	(21.2)	241	20.8	39	(8.8)	48	8.6
Mild RI (60-<90)	114	(28.4)	144	27.5	20	(10.0)	22	8.6
Moderate RI (30-<60)	4	(22.2)	5	21.5	3	(30.0)	3	22.4
Gastrooesophageal reflux disease								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	47 (5.3)	53	4.6	15 (3.4)	16	2.9
Mild RI (60-<90)	32 (8.0)	36	6.9	5 (2.5)	5	1.9
Moderate RI (30-<60)	3 (16.7)	3	12.9	0		
Irritable bowel syndrome						
Normal (>=90)	4 (0.5)	5	0.4	1 (0.2)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Frequent bowel movements						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Dyschezia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Impaired gastric emptying						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Bowel movement irregularity						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Defaecation urgency						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Infrequent bowel movements						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Change of bowel habit						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal hypermotility						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal motility disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oesophageal achalasia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal inflammatory conditions						
Normal (>=90)	53	(6.0)	71 6.1	7	(1.6)	8 1.4
Mild RI (60-<90)	17	(4.2)	22 4.2	5	(2.5)	5 1.9
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastritis						
Normal (>=90)	39 (4.4)	52	4.5	4 (0.9)	5	0.9
Mild RI (60-<90)	11 (2.7)	15	2.9	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Colitis						
Normal (>=90)	6 (0.7)	8	0.7	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Reflux gastritis						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Enteritis						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Duodenitis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Gastrointestinal inflammation						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Oesophagitis						
Normal (>=90)	1 (0.1)	1	<0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Crohn's disease								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Chronic gastritis								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				2	(1.0)	2	0.8
Moderate RI (30-<60)	0				0			
Colitis ischaemic								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Eosinophilic oesophagitis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Gastroenteritis eosinophilic								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Epiploic appendagitis								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Inflammatory bowel disease						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Benign neoplasms gastrointestinal						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	4 (1.0)	4	0.8	3 (1.5)	3	1.2
Moderate RI (30-<60)	2 (11.1)	2	8.6	0		
Large intestine polyp						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	4 (1.0)	4	0.8	3 (1.5)	3	1.2
Moderate RI (30-<60)	2 (11.1)	2	8.6	0		
Gastric polyps						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Dental and gingival conditions						
Normal (>=90)	19 (2.1)	21	1.8	19 (4.3)	20	3.6
Mild RI (60-<90)	7 (1.7)	10	1.9	10 (5.0)	12	4.7
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Toothache						
Normal (>=90)	10 (1.1)	12	1.0	13 (2.9)	14	2.5
Mild RI (60-<90)	6 (1.5)	7	1.3	4 (2.0)	4	1.6
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dental caries						
Normal (>=90)	3 (0.3)	3	0.3	6 (1.3)	6	1.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	2 0.4	4	(2.0)	4 1.6
Moderate RI (30-<60)	0			0		
Tooth impacted						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Gingival bleeding						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gingival disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gingival pain						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Noninfective gingivitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Periodontal disease						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Tooth loss						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Dental necrosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Dental pulp disorder						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Tooth disorder						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Gastrointestinal haemorrhages NEC						
Normal (>=90)	9	(1.0)	10 0.9	4	(0.9)	5 0.9
Mild RI (60-<90)	5	(1.2)	5 1.0	2	(1.0)	2 0.8
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Lower gastrointestinal haemorrhage						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Haematochezia						
Normal (>=90)	3	(0.3)	3 0.3	1	(0.2)	2 0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	4 (1.0)	4	0.8	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Rectal haemorrhage						
Normal (>=90)	6 (0.7)	6	0.5	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Haematemesis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Melaena						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Upper gastrointestinal haemorrhage						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal conditions NEC						
Normal (>=90)	36 (4.1)	54	4.7	11 (2.5)	15	2.7
Mild RI (60-<90)	12 (3.0)	13	2.5	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Food poisoning						
Normal (>=90)	13 (1.5)	13	1.1	4 (0.9)	6	1.1
Mild RI (60-<90)	5 (1.2)	5	1.0	0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hyperchlorhydria						
Normal (>=90)	17	(1.9)	34 2.9	3	(0.7)	5 0.9
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Gastrointestinal disorder						
Normal (>=90)	3	(0.3)	4 0.3	4	(0.9)	4 0.7
Mild RI (60-<90)	2	(0.5)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Anal fistula						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Gastric mucosal hypertrophy						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Barrett's oesophagus						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Functional gastrointestinal disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Diverticular disorders						
Normal (>=90)	5	(0.6)	5 0.4	1	(0.2)	1 0.2

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	4 (2.0)	4	1.6
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Diverticulum						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	4 (2.0)	4	1.6
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Salivary gland conditions						
Normal (>=90)	15 (1.7)	15	1.3	5 (1.1)	5	0.9
Mild RI (60-<90)	12 (3.0)	12	2.3	3 (1.5)	4	1.6
Moderate RI (30-<60)	0			0		
Dry mouth						
Normal (>=90)	15 (1.7)	15	1.3	4 (0.9)	4	0.7
Mild RI (60-<90)	10 (2.5)	10	1.9	3 (1.5)	4	1.6
Moderate RI (30-<60)	0			0		
Salivary gland calculus						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Salivary gland cyst						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Salivary gland enlargement						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal vascular conditions						
Normal (>=90)	18 (2.0)	20	1.7	3 (0.7)	3	0.5
Mild RI (60-<90)	10 (2.5)	10	1.9	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Haemorrhoids						
Normal (>=90)	16 (1.8)	17	1.5	1 (0.2)	1	0.2
Mild RI (60-<90)	10 (2.5)	10	1.9	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Haemorrhoidal haemorrhage						
Normal (>=90)	1 (0.1)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Haemorrhoids thrombosed						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Abdominal hernias and other abdominal wall conditions						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	5 (1.2)	6	1.1	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Hiatus hernia						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	4 (1.0)	5	1.0	0		
Moderate RI (30-<60)	0			0		
Abdominal hernia						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Umbilical hernia						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Anal and rectal conditions NEC						
Normal (>=90)	5	(0.6)	7 0.6	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Anal fissure						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Anal pruritus						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Anorectal discomfort						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Proctalgia						
Normal (>=90)	2	(0.2)	3 0.3	0		
Mild RI (60-<90)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Rectal fissure						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oral soft tissue conditions						
Normal (>=90)	7	(0.8)	8 0.7	5	(1.1)	5 0.9
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Lip swelling						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Aphthous ulcer						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cheilitis						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Lip disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Mouth ulceration						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Odynophagia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Paraesthesia oral						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Stomatitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oral mucosal eruption						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal ulceration and perforation						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Oesophageal ulcer						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Duodenal ulcer						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastric ulcer						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Large intestine perforation						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Peptic ulcer						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal stenosis and obstruction						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Volvulus						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Ileus						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oesophageal stenosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Intestinal obstruction						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Malabsorption conditions						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Coeliac disease						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Exocrine pancreas conditions						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pancreatitis acute						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Peritoneal and retroperitoneal conditions								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Pneumoperitoneum								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Tongue conditions								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Glossodynia								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Infections and infestations								
Normal (>=90)	483	(54.5)	1085	93.5	247	(55.5)	527	94.2
Mild RI (60-<90)	220	(54.9)	514	98.3	120	(60.0)	267	103.9
Moderate RI (30-<60)	11	(61.1)	16	68.9	5	(50.0)	8	59.9
Infections - pathogen unspecified								

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	417	(47.0)	816	70.4	206	(46.3)	397	71.0
Mild RI (60-<90)	200	(49.9)	419	80.1	105	(52.5)	207	80.6
Moderate RI (30-<60)	9	(50.0)	12	51.6	3	(30.0)	6	44.9
Nasopharyngitis								
Normal (>=90)	189	(21.3)	310	26.7	87	(19.6)	136	24.3
Mild RI (60-<90)	92	(22.9)	170	32.5	45	(22.5)	78	30.4
Moderate RI (30-<60)	0				1	(10.0)	2	15.0
Bronchitis								
Normal (>=90)	30	(3.4)	32	2.8	14	(3.1)	16	2.9
Mild RI (60-<90)	13	(3.2)	15	2.9	11	(5.5)	12	4.7
Moderate RI (30-<60)	4	(22.2)	5	21.5	0			
Upper respiratory tract infection								
Normal (>=90)	74	(8.3)	105	9.1	52	(11.7)	69	12.3
Mild RI (60-<90)	39	(9.7)	51	9.8	27	(13.5)	45	17.5
Moderate RI (30-<60)	1	(5.6)	2	8.6	1	(10.0)	2	15.0
Gastroenteritis								
Normal (>=90)	57	(6.4)	70	6.0	22	(4.9)	27	4.8
Mild RI (60-<90)	27	(6.7)	33	6.3	8	(4.0)	11	4.3
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Sinusitis								
Normal (>=90)	47	(5.3)	57	4.9	24	(5.4)	27	4.8
Mild RI (60-<90)	23	(5.7)	26	5.0	11	(5.5)	12	4.7
Moderate RI (30-<60)	1	(5.6)	1	4.3	1	(10.0)	1	7.5
Urinary tract infection								
Normal (>=90)	37	(4.2)	45	3.9	19	(4.3)	23	4.1
Mild RI (60-<90)	31	(7.7)	38	7.3	9	(4.5)	11	4.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Ear infection						
Normal (>=90)	7 (0.8)	8	0.7	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Folliculitis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Large intestine infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Cystitis						
Normal (>=90)	13 (1.5)	15	1.3	2 (0.4)	2	0.4
Mild RI (60-<90)	6 (1.5)	6	1.1	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Rhinitis						
Normal (>=90)	13 (1.5)	16	1.4	7 (1.6)	11	2.0
Mild RI (60-<90)	6 (1.5)	9	1.7	2 (1.0)	3	1.2
Moderate RI (30-<60)	0			0		
Laryngitis						
Normal (>=90)	9 (1.0)	9	0.8	3 (0.7)	4	0.7
Mild RI (60-<90)	5 (1.2)	5	1.0	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Acute sinusitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	6 (0.7)	7	0.6	4 (0.9)	5	0.9
Mild RI (60-<90)	5 (1.2)	5	1.0	4 (2.0)	4	1.6
Moderate RI (30-<60)	0			0		
Pneumonia						
Normal (>=90)	8 (0.9)	10	0.9	5 (1.1)	5	0.9
Mild RI (60-<90)	3 (0.7)	4	0.8	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Tonsillitis						
Normal (>=90)	10 (1.1)	13	1.1	6 (1.3)	8	1.4
Mild RI (60-<90)	2 (0.5)	2	0.4	4 (2.0)	4	1.6
Moderate RI (30-<60)	0			0		
Tooth abscess						
Normal (>=90)	3 (0.3)	3	0.3	4 (0.9)	5	0.9
Mild RI (60-<90)	5 (1.2)	5	1.0	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Vaginal infection						
Normal (>=90)	9 (1.0)	11	0.9	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Pharyngitis						
Normal (>=90)	13 (1.5)	13	1.1	6 (1.3)	6	1.1
Mild RI (60-<90)	0			3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Tooth infection						
Normal (>=90)	10 (1.1)	11	0.9	5 (1.1)	5	0.9
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Conjunctivitis						
Normal (>=90)	3	(0.3)	3 0.3	3	(0.7)	3 0.5
Mild RI (60-<90)	4	(1.0)	4 0.8	0		
Moderate RI (30-<60)	0			0		
Lower respiratory tract infection						
Normal (>=90)	7	(0.8)	8 0.7	11	(2.5)	15 2.7
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Gastrointestinal infection						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	4	(1.0)	6 1.1	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Eye infection						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Appendicitis						
Normal (>=90)	3	(0.3)	3 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Kidney infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Pulpitis dental						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Otitis media						
Normal (>=90)	6 (0.7)	6	0.5	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hordeolum						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Breast abscess						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Chronic sinusitis						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Gingivitis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Infected bite						
Normal (>=90)	2 (0.2)	2	0.2	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Pyelonephritis						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Abdominal wall abscess						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Diarrhoea infectious						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Postoperative wound infection						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Pharyngotonsillitis						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Subcutaneous abscess						
Normal (>=90)	3	(0.3)	3 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Appendicitis perforated						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Device related infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Diverticulitis						
Normal (>=90)	0			2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Epididymitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Eyelid infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Groin abscess						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Mastitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Osteomyelitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Paronychia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Parotitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Perirectal abscess						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Abscess						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Atypical pneumonia						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Infection						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Localised infection								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				2	(1.0)	2	0.8
Moderate RI (30-<60)	0				0			
Omphalitis								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Otitis externa								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Periodontitis								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Abdominal abscess								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Abscess limb								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Bartholinitis						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Carbuncle						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Endometritis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Fracture infection						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Haematoma infection						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nail infection						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oophoritis						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Oral infection								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Parasitic gastroenteritis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Peritonitis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Prostate infection								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Purulence								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Respiratory tract infection								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Salpingitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Sepsis syndrome						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin infection						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Arthritis infective						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cervicitis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Empyema						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Gastric infection						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Infected dermal cyst						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lymphangitis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neutropenic sepsis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Otitis media acute						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Peritonsillar abscess						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Peritonsillitis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Root canal infection								
Normal (>=90)	0				2	(0.4)	2	0.4
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Septic shock								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Tracheitis								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Wound infection								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Viral infectious disorders								
Normal (>=90)	145	(16.3)	192	16.6	73	(16.4)	96	17.2
Mild RI (60-<90)	47	(11.7)	54	10.3	29	(14.5)	39	15.2
Moderate RI (30-<60)	2	(11.1)	2	8.6	1	(10.0)	1	7.5
Influenza								
Normal (>=90)	69	(7.8)	91	7.8	46	(10.3)	54	9.7
Mild RI (60-<90)	20	(5.0)	21	4.0	17	(8.5)	25	9.7
Moderate RI (30-<60)	0				0			
Gastrointestinal viral infection								

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	4 (0.5)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Gastroenteritis viral						
Normal (>=90)	29 (3.3)	30	2.6	9 (2.0)	10	1.8
Mild RI (60-<90)	13 (3.2)	14	2.7	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Gastroenteritis astroviral						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Herpes zoster						
Normal (>=90)	9 (1.0)	10	0.9	10 (2.2)	10	1.8
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Viral infection						
Normal (>=90)	13 (1.5)	19	1.6	4 (0.9)	4	0.7
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Viral upper respiratory tract infection						
Normal (>=90)	6 (0.7)	6	0.5	3 (0.7)	4	0.7
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Herpes simplex						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Oral herpes						
Normal (>=90)	2 (0.2)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Ear infection viral						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastroenteritis norovirus						
Normal (>=90)	5 (0.6)	6	0.5	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Herpes virus infection						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Dengue fever						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Viral pharyngitis						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cytomegalovirus infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Infectious mononucleosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Oral viral infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Parainfluenzae virus infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Respiratory syncytial virus infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Respiratory tract infection viral						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Chronic hepatitis B						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Genital herpes zoster						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hepatitis E						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Papilloma viral infection						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Varicella						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vestibular neuronitis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Viral sinusitis						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Bronchitis viral						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Conjunctivitis viral						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hand-foot-and-mouth disease						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Meningitis viral						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Viral rhinitis						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bacterial infectious disorders						
Normal (>=90)	33 (3.7)	38	3.3	18 (4.0)	19	3.4
Mild RI (60-<90)	22 (5.5)	23	4.4	8 (4.0)	11	4.3
Moderate RI (30-<60)	2 (11.1)	2	8.6	1 (10.0)	1	7.5
Pharyngitis streptococcal						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	7 (0.8)	7	0.6	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	3	0.6	3 (1.5)	3	1.2
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Lyme disease						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Cellulitis						
Normal (>=90)	2 (0.2)	2	0.2	4 (0.9)	4	0.7
Mild RI (60-<90)	7 (1.7)	7	1.3	3 (1.5)	4	1.6
Moderate RI (30-<60)	0			0		
Ear infection bacterial						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Helicobacter infection						
Normal (>=90)	3 (0.3)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Staphylococcal infection						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Bacterial vaginosis						
Normal (>=90)	4 (0.5)	7	0.6	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Erysipelas						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Furuncle						
Normal (>=90)	3	(0.3)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin bacterial infection						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Syphilis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Helicobacter gastritis						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bacterial colitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bacterial vulvovaginitis						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Genital infection bacterial								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Pharyngitis bacterial								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Salmonellosis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Sinusitis bacterial								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Tonsillitis bacterial								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Typhoid fever								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0			0			
Bacteriuria							
Normal (>=90)	0			1	(0.2)	1	0.2
Mild RI (60-<90)	0			0			
Moderate RI (30-<60)	0			0			
Gastric ulcer helicobacter							
Normal (>=90)	0			1	(0.2)	1	0.2
Mild RI (60-<90)	0			0			
Moderate RI (30-<60)	0			0			
Listeriosis							
Normal (>=90)	0			0			
Mild RI (60-<90)	0			1	(0.5)	1	0.4
Moderate RI (30-<60)	0			0			
Staphylococcal sepsis							
Normal (>=90)	0			1	(0.2)	1	0.2
Mild RI (60-<90)	0			0			
Moderate RI (30-<60)	0			0			
Streptococcal urinary tract infection							
Normal (>=90)	0			1	(0.2)	1	0.2
Mild RI (60-<90)	0			0			
Moderate RI (30-<60)	0			0			
Upper respiratory tract infection bacterial							
Normal (>=90)	0			0			
Mild RI (60-<90)	0			1	(0.5)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Fungal infectious disorders						
Normal (>=90)	29	(3.3)	35 3.0	13	(2.9)	14 2.5
Mild RI (60-<90)	16	(4.0)	18 3.4	9	(4.5)	10 3.9
Moderate RI (30-<60)	0			0		
Fungal infection						
Normal (>=90)	2	(0.2)	3 0.3	3	(0.7)	3 0.5
Mild RI (60-<90)	8	(2.0)	8 1.5	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Vulvovaginal mycotic infection						
Normal (>=90)	8	(0.9)	9 0.8	1	(0.2)	1 0.2
Mild RI (60-<90)	3	(0.7)	4 0.8	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Vulvovaginal candidiasis						
Normal (>=90)	4	(0.5)	6 0.5	3	(0.7)	3 0.5
Mild RI (60-<90)	1	(0.2)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Tinea pedis						
Normal (>=90)	6	(0.7)	6 0.5	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Body tinea						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Fungal skin infection						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Onychomycosis						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	4	1.6
Moderate RI (30-<60)	0			0		
Tinea cruris						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dermatophytosis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin candida						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Candida infection						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Dermatophytosis of nail						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Tinea capitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Tinea infection						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oral candidiasis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Otitis externa fungal						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Protozoal infectious disorders						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Trichomoniasis						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Toxoplasmosis						

Adverse events with onset prior to randomisation are not included.
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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Chlamydial infectious disorders								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Chlamydial infection								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Ectoparasitic disorders								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Acarodermatitis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Nervous system disorders								
Normal (>=90)	269	(30.3)	523	45.1	94	(21.1)	147	26.3
Mild RI (60-<90)	114	(28.4)	213	40.7	45	(22.5)	72	28.0
Moderate RI (30-<60)	8	(44.4)	22	94.7	2	(20.0)	3	22.4
Neurological disorders NEC								
Normal (>=90)	118	(13.3)	157	13.5	29	(6.5)	43	7.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	56 (14.0)	76	14.5	16 (8.0)	23	9.0
Moderate RI (30-<60)	7 (38.9)	15	64.6	2 (20.0)	2	15.0
Dizziness						
Normal (>=90)	62 (7.0)	74	6.4	16 (3.6)	23	4.1
Mild RI (60-<90)	31 (7.7)	47	9.0	7 (3.5)	12	4.7
Moderate RI (30-<60)	5 (27.8)	9	38.7	0		
Syncope						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	5 (1.2)	5	1.0	2 (1.0)	2	0.8
Moderate RI (30-<60)	3 (16.7)	3	12.9	0		
Paraesthesia						
Normal (>=90)	9 (1.0)	11	0.9	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	4	0.8	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	2	8.6	0		
Aphasia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dysgeusia						
Normal (>=90)	15 (1.7)	21	1.8	2 (0.4)	9	1.6
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Taste disorder						
Normal (>=90)	6 (0.7)	8	0.7	0		
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Lethargy						
Normal (>=90)	4 (0.5)	4	0.3	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Hypoaesthesia						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Somnolence						
Normal (>=90)	7 (0.8)	9	0.8	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neuralgia						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dizziness postural						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Hyperaesthesia						
Normal (>=90)	3 (0.3)	5	0.4	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Balance disorder						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Burning sensation						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Presyncope						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dysaesthesia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Hyporeflexia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Allodynia						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ageusia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Dysarthria								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Loss of consciousness								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Restless legs syndrome								
Normal (>=90)	1	(0.1)	2	0.2	1	(0.2)	1	0.2
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Sensory disturbance								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Vertigo CNS origin								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Sensory loss								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Headaches								
Normal (>=90)	163	(18.4)	330	28.5	66	(14.8)	87	15.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	62	(15.5)	116	22.2	23	(11.5)	31	12.1
Moderate RI (30-<60)	4	(22.2)	5	21.5	0			
Headache								
Normal (>=90)	137	(15.4)	281	24.2	57	(12.8)	74	13.2
Mild RI (60-<90)	58	(14.5)	102	19.5	23	(11.5)	30	11.7
Moderate RI (30-<60)	3	(16.7)	4	17.2	0			
Tension headache								
Normal (>=90)	3	(0.3)	3	0.3	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Migraine								
Normal (>=90)	26	(2.9)	39	3.4	8	(1.8)	10	1.8
Mild RI (60-<90)	6	(1.5)	13	2.5	1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Sinus headache								
Normal (>=90)	4	(0.5)	4	0.3	1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Migraine with aura								
Normal (>=90)	2	(0.2)	2	0.2	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Occipital neuralgia								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Peripheral neuropathies						
Normal (>=90)	7 (0.8)	8	0.7	4 (0.9)	4	0.7
Mild RI (60-<90)	4 (1.0)	4	0.8	4 (2.0)	5	1.9
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Neuropathy peripheral						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Nerve compression						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Carpal tunnel syndrome						
Normal (>=90)	3 (0.3)	4	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Peripheral sensory neuropathy						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Peroneal nerve palsy						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Radial nerve compression						
Normal (>=90)	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Movement disorders (incl parkinsonism)						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	4 (1.0)	4	0.8	2 (1.0)	3	1.2
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Essential tremor						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Tremor						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	4 (1.0)	4	0.8	2 (1.0)	3	1.2
Moderate RI (30-<60)	0			0		
Spinal cord and nerve root disorders						
Normal (>=90)	12 (1.4)	14	1.2	4 (0.9)	4	0.7
Mild RI (60-<90)	8 (2.0)	8	1.5	9 (4.5)	9	3.5
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Sciatica						
Normal (>=90)	9 (1.0)	11	0.9	1 (0.2)	1	0.2
Mild RI (60-<90)	5 (1.2)	5	1.0	6 (3.0)	6	2.3
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Cervicobrachial syndrome						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Lumbar radiculopathy						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Spinal cord compression						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Cervical radiculopathy						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Lumbosacral radiculopathy						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Mental impairment disorders						
Normal (>=90)	3	(0.3)	3 0.3	2	(0.4)	3 0.5
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Memory impairment						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Disturbance in attention						
Normal (>=90)	0			2	(0.4)	3 0.5

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Amnesia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Dementia Alzheimer's type						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cranial nerve disorders (excl neoplasms)						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Anosmia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Cranial nerve disorder						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Parosmia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0			0				
Sleep disturbances (incl subtypes)								
Normal (>=90)	3	(0.3)	3	0.3	1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Poor quality sleep								
Normal (>=90)	3	(0.3)	3	0.3	1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Central nervous system vascular disorders								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Cerebral infarction								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Ischaemic stroke								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Increased intracranial pressure and hydrocephalus								
Normal (>=90)	1	(0.1)	2	0.2	0			
Mild RI (60-<90)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Idiopathic intracranial hypertension						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neurological disorders of the eye						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Visual field defect						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neuromuscular disorders						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Autonomic nervous system imbalance						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Demyelinating disorders						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Multiple sclerosis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Seizures (incl subtypes)								
Normal (>=90)	0				2	(0.4)	2	0.4
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Partial seizures								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Psychogenic seizure								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Musculoskeletal and connective tissue disorders								
Normal (>=90)	209	(23.6)	340	29.3	114	(25.6)	184	32.9
Mild RI (60-<90)	121	(30.2)	200	38.2	68	(34.0)	114	44.4
Moderate RI (30-<60)	8	(44.4)	18	77.5	4	(40.0)	6	44.9
Musculoskeletal and connective tissue disorders NEC								
Normal (>=90)	121	(13.6)	158	13.6	58	(13.0)	80	14.3
Mild RI (60-<90)	61	(15.2)	81	15.5	40	(20.0)	51	19.9
Moderate RI (30-<60)	5	(27.8)	5	21.5	1	(10.0)	1	7.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Back pain						
Normal (>=90)	69 (7.8)	77	6.6	34 (7.6)	34	6.1
Mild RI (60-<90)	36 (9.0)	42	8.0	19 (9.5)	21	8.2
Moderate RI (30-<60)	2 (11.1)	2	8.6	1 (10.0)	1	7.5
Pain in extremity						
Normal (>=90)	30 (3.4)	33	2.8	12 (2.7)	14	2.5
Mild RI (60-<90)	13 (3.2)	14	2.7	12 (6.0)	14	5.5
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Musculoskeletal pain						
Normal (>=90)	22 (2.5)	22	1.9	11 (2.5)	13	2.3
Mild RI (60-<90)	8 (2.0)	8	1.5	5 (2.5)	5	1.9
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Neck pain						
Normal (>=90)	12 (1.4)	13	1.1	6 (1.3)	6	1.1
Mild RI (60-<90)	6 (1.5)	7	1.3	3 (1.5)	3	1.2
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Musculoskeletal chest pain						
Normal (>=90)	2 (0.2)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	6 (1.5)	6	1.1	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Musculoskeletal stiffness						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Flank pain						
Normal (>=90)	2 (0.2)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Axillary mass						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Plantar fasciitis						
Normal (>=90)	3	(0.3)	3 0.3	4	(0.9)	4 0.7
Mild RI (60-<90)	0			2	(1.0)	3 1.2
Moderate RI (30-<60)	0			0		
Dupuytren's contracture						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Musculoskeletal discomfort						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Groin pain						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Limb mass						
Normal (>=90)	0			1	(0.2)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Muscle contracture								
Normal (>=90)	0				2	(0.4)	2	0.4
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Neck mass								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Joint disorders								
Normal (>=90)	77	(8.7)	94	8.1	45	(10.1)	55	9.8
Mild RI (60-<90)	53	(13.2)	70	13.4	29	(14.5)	38	14.8
Moderate RI (30-<60)	3	(16.7)	5	21.5	1	(10.0)	1	7.5
Arthralgia								
Normal (>=90)	50	(5.6)	54	4.7	22	(4.9)	24	4.3
Mild RI (60-<90)	28	(7.0)	34	6.5	20	(10.0)	22	8.6
Moderate RI (30-<60)	3	(16.7)	4	17.2	1	(10.0)	1	7.5
Joint stiffness								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Osteoarthritis								
Normal (>=90)	13	(1.5)	17	1.5	13	(2.9)	14	2.5
Mild RI (60-<90)	10	(2.5)	11	2.1	5	(2.5)	6	2.3
Moderate RI (30-<60)	0				0			
Spinal osteoarthritis								
Normal (>=90)	8	(0.9)	8	0.7	0			

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	4 (1.0)	5	1.0	0		
Moderate RI (30-<60)	0			0		
Arthritis						
Normal (>=90)	5 (0.6)	5	0.4	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	3	0.6	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Joint swelling						
Normal (>=90)	4 (0.5)	4	0.3	4 (0.9)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Rotator cuff syndrome						
Normal (>=90)	3 (0.3)	3	0.3	5 (1.1)	5	0.9
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Vertebral foraminal stenosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	3 (0.7)	4	0.8	0		
Moderate RI (30-<60)	0			0		
Facet joint syndrome						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Arthropathy						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Periarthritis						
Normal (>=90)	0			1	(0.2)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Vertebral osteophyte						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Spondylitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Chondromalacia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Haemarthrosis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Joint noise						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Joint range of motion decreased						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Joint space narrowing						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Polyarthritis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Rheumatoid arthritis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Spondyloarthropathy						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Muscle disorders						
Normal (>=90)	40	(4.5)	45 3.9	15	(3.4)	20 3.6
Mild RI (60-<90)	14	(3.5)	14 2.7	7	(3.5)	8 3.1
Moderate RI (30-<60)	4	(22.2)	5 21.5	1	(10.0)	1 7.5
Muscle spasms						
Normal (>=90)	10	(1.1)	10 0.9	5	(1.1)	5 0.9
Mild RI (60-<90)	7	(1.7)	7 1.3	4	(2.0)	5 1.9
Moderate RI (30-<60)	2	(11.1)	2 8.6	1	(10.0)	1 7.5

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Myalgia						
Normal (>=90)	18 (2.0)	20	1.7	7 (1.6)	12	2.1
Mild RI (60-<90)	4 (1.0)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	2	8.6	0		
Muscular weakness						
Normal (>=90)	4 (0.5)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Fibromyalgia						
Normal (>=90)	2 (0.2)	2	0.2	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Myosclerosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Myofascial pain syndrome						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Muscle disorder						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Muscle fatigue						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Muscle tightness						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Muscle twitching						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Myalgia intercostal						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Torticollis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)						
Normal (>=90)	8	(0.9)	8 0.7	7	(1.6)	8 1.4
Mild RI (60-<90)	10	(2.5)	15 2.9	4	(2.0)	5 1.9
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Finger deformity						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Intervertebral disc protrusion						
Normal (>=90)	4 (0.5)	4	0.3	3 (0.7)	4	0.7
Mild RI (60-<90)	4 (1.0)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Intervertebral disc degeneration						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	5 (1.2)	7	1.3	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Scoliosis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Intervertebral disc displacement						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Kyphoscoliosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Spinal stenosis						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Cervical spinal stenosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Spondylolisthesis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Foot deformity						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Intervertebral disc annular tear						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Kyphosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Synovial and bursal disorders						
Normal (>=90)	12	(1.4)	12 1.0	3	(0.7)	3 0.5
Mild RI (60-<90)	3	(0.7)	3 0.6	2	(1.0)	2 0.8
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Bursitis						
Normal (>=90)	8	(0.9)	8 0.7	2	(0.4)	2 0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Synovial cyst						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Synovitis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bursal fluid accumulation						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Bone disorders (excl congenital and fractures)						
Normal (>=90)	5 (0.6)	6	0.5	8 (1.8)	8	1.4
Mild RI (60-<90)	5 (1.2)	5	1.0	6 (3.0)	6	2.3
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Exostosis						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Osteopenia						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Pain in jaw						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Osteonecrosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Osteoporosis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Bone cyst						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Coccydynia						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Metatarsalgia						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Pubic pain						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Tendon, ligament and cartilage disorders						
Normal (>=90)	15	(1.7)	16 1.4	8	(1.8)	9 1.6
Mild RI (60-<90)	10	(2.5)	11 2.1	4	(2.0)	4 1.6
Moderate RI (30-<60)	0			1	(10.0)	2 15.0
Tendonitis						
Normal (>=90)	7	(0.8)	8 0.7	6	(1.3)	7 1.3
Mild RI (60-<90)	6	(1.5)	6 1.1	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			1	(10.0)	2 15.0
Costochondritis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Tenosynovitis						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Tendon discomfort						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Tendon pain						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Trigger finger						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Tendon disorder						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Osteochondrosis						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Posterior tibial tendon dysfunction						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Connective tissue disorders (excl congenital)						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Myofascitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Sjogren's syndrome								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Systemic lupus erythematosus								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Systemic scleroderma								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				1	(10.0)	1	7.5
General disorders and administration site conditions								
Normal (>=90)	195	(22.0)	316	27.2	88	(19.8)	151	27.0
Mild RI (60-<90)	91	(22.7)	139	26.6	41	(20.5)	66	25.7
Moderate RI (30-<60)	5	(27.8)	10	43.0	2	(20.0)	5	37.4
General system disorders NEC								
Normal (>=90)	151	(17.0)	225	19.4	55	(12.4)	74	13.2
Mild RI (60-<90)	71	(17.7)	92	17.6	29	(14.5)	35	13.6
Moderate RI (30-<60)	3	(16.7)	7	30.1	2	(20.0)	4	29.9
Fatigue								
Normal (>=90)	64	(7.2)	75	6.5	18	(4.0)	18	3.2
Mild RI (60-<90)	38	(9.5)	41	7.8	9	(4.5)	10	3.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	2	(11.1)	4	17.2	1	(10.0)	1	7.5
Asthenia								
Normal (>=90)	25	(2.8)	42	3.6	8	(1.8)	9	1.6
Mild RI (60-<90)	9	(2.2)	10	1.9	3	(1.5)	3	1.2
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Pain								
Normal (>=90)	15	(1.7)	16	1.4	5	(1.1)	5	0.9
Mild RI (60-<90)	5	(1.2)	6	1.1	2	(1.0)	2	0.8
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Chills								
Normal (>=90)	5	(0.6)	5	0.4	1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	1	(0.5)	1	0.4
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Early satiety								
Normal (>=90)	17	(1.9)	17	1.5	2	(0.4)	2	0.4
Mild RI (60-<90)	9	(2.2)	9	1.7	0			
Moderate RI (30-<60)	0				0			
Malaise								
Normal (>=90)	12	(1.4)	14	1.2	4	(0.9)	5	0.9
Mild RI (60-<90)	4	(1.0)	5	1.0	0			
Moderate RI (30-<60)	0				0			
Influenza like illness								
Normal (>=90)	14	(1.6)	15	1.3	8	(1.8)	8	1.4
Mild RI (60-<90)	3	(0.7)	3	0.6	5	(2.5)	5	1.9
Moderate RI (30-<60)	0				0			
Chest discomfort								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	5 (0.6)	5	0.4	0		
Mild RI (60-<90)	4 (1.0)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	2	15.0
Non-cardiac chest pain						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Hunger						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Oedema peripheral						
Normal (>=90)	2 (0.2)	2	0.2	7 (1.6)	7	1.3
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Chest pain						
Normal (>=90)	2 (0.2)	2	0.2	5 (1.1)	5	0.9
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Thirst						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Feeling cold						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Feeling hot						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Ill-defined disorder						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Sensation of foreign body						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Axillary pain						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Sluggishness						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Hernia						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Peripheral swelling						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	2	(0.2)	2 0.2	2	(0.4)	2 0.4
Mild RI (60-<90)	0			3	(1.5)	3 1.2
Moderate RI (30-<60)	0			0		
Swelling						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Swelling face						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Crying						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Fat tissue increased						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hangover						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Inflammation						
Normal (>=90)	1	(0.1)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Pseudocyst								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Sense of oppression								
Normal (>=90)	1	(0.1)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Discomfort								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Facial pain								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Granuloma								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Gravitational oedema								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Temperature intolerance								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Administration site reactions						
Normal (>=90)	45 (5.1)	59	5.1	30 (6.7)	56	10.0
Mild RI (60-<90)	18 (4.5)	37	7.1	13 (6.5)	25	9.7
Moderate RI (30-<60)	2 (11.1)	3	12.9	1 (10.0)	1	7.5
Injection site bruising						
Normal (>=90)	18 (2.0)	19	1.6	17 (3.8)	21	3.8
Mild RI (60-<90)	9 (2.2)	11	2.1	9 (4.5)	13	5.1
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Injection site pain						
Normal (>=90)	11 (1.2)	12	1.0	10 (2.2)	13	2.3
Mild RI (60-<90)	7 (1.7)	11	2.1	5 (2.5)	7	2.7
Moderate RI (30-<60)	1 (5.6)	1	4.3	1 (10.0)	1	7.5
Infusion site extravasation						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Injection site pruritus						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	4 (1.0)	4	0.8	0		
Moderate RI (30-<60)	0			0		
Injection site reaction						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	3 (0.7)	3	0.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Injection site mass						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	3	(1.5)	3 1.2
Moderate RI (30-<60)	0			0		
Injection site inflammation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Injection site erythema						
Normal (>=90)	3	(0.3)	3 0.3	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injection site haematoma						
Normal (>=90)	3	(0.3)	8 0.7	4	(0.9)	12 2.1
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injection site swelling						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Injection site urticaria						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Application site haematoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injection site haemorrhage						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injection site paraesthesia						
Normal (>=90)	2	(0.2)	2 0.2	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injection site induration						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vessel puncture site bruise						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vessel puncture site rash						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Application site bruise						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Puncture site pain						
Normal (>=90)	0			1 (0.2)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Body temperature conditions						
Normal (>=90)	22 (2.5)	28	2.4	12 (2.7)	16	2.9
Mild RI (60-<90)	5 (1.2)	5	1.0	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Pyrexia						
Normal (>=90)	22 (2.5)	28	2.4	12 (2.7)	16	2.9
Mild RI (60-<90)	5 (1.2)	5	1.0	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Tissue disorders NEC						
Normal (>=90)	1 (0.1)	1	<0.1	5 (1.1)	5	0.9
Mild RI (60-<90)	4 (1.0)	4	0.8	0		
Moderate RI (30-<60)	0			0		
Cyst						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Nodule						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Dysplasia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Fat necrosis								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Hyperplasia								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Complications associated with device								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	1	(0.2)	1	0.2	1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Vascular stent occlusion								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Injury associated with device								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Therapeutic and nontherapeutic effects (excl toxicity)								
Normal (>=90)	2	(0.2)	2	0.2	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Withdrawal syndrome								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Injury, poisoning and procedural complications								
Normal (>=90)	117	(13.2)	168	14.5	77	(17.3)	110	19.7
Mild RI (60-<90)	65	(16.2)	89	17.0	41	(20.5)	63	24.5
Moderate RI (30-<60)	6	(33.3)	7	30.1	3	(30.0)	3	22.4
Injuries NEC								
Normal (>=90)	81	(9.1)	115	9.9	62	(13.9)	87	15.6
Mild RI (60-<90)	42	(10.5)	50	9.6	32	(16.0)	41	16.0
Moderate RI (30-<60)	3	(16.7)	3	12.9	2	(20.0)	2	15.0
Fall								
Normal (>=90)	11	(1.2)	11	0.9	9	(2.0)	16	2.9
Mild RI (60-<90)	7	(1.7)	7	1.3	3	(1.5)	3	1.2
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Arthropod bite								
Normal (>=90)	5	(0.6)	5	0.4	6	(1.3)	6	1.1
Mild RI (60-<90)	3	(0.7)	3	0.6	1	(0.5)	1	0.4
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Tooth fracture								
Normal (>=90)	3	(0.3)	3	0.3	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	1 (10.0)	1	7.5
Ligament sprain						
Normal (>=90)	18 (2.0)	21	1.8	13 (2.9)	13	2.3
Mild RI (60-<90)	3 (0.7)	3	0.6	6 (3.0)	7	2.7
Moderate RI (30-<60)	0			0		
Muscle strain						
Normal (>=90)	11 (1.2)	12	1.0	8 (1.8)	8	1.4
Mild RI (60-<90)	6 (1.5)	6	1.1	7 (3.5)	7	2.7
Moderate RI (30-<60)	0			0		
Contusion						
Normal (>=90)	11 (1.2)	13	1.1	10 (2.2)	14	2.5
Mild RI (60-<90)	4 (1.0)	6	1.1	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Arthropod sting						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	4 (1.0)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Skin laceration						
Normal (>=90)	8 (0.9)	8	0.7	3 (0.7)	4	0.7
Mild RI (60-<90)	1 (0.2)	1	0.2	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Skin abrasion						
Normal (>=90)	1 (0.1)	4	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	4 (1.0)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Limb injury						
Normal (>=90)	5 (0.6)	5	0.4	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Epicondylitis						
Normal (>=90)	2 (0.2)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	2 (0.5)	2	0.4	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Animal bite						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Concussion						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Back injury						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Muscle rupture						
Normal (>=90)	2 (0.2)	2	0.2	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Ligament rupture						
Normal (>=90)	4 (0.5)	4	0.3	1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Wound								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	1	(0.2)	1	0.2	2	(1.0)	2	0.8
Moderate RI (30-<60)	0				0			
Road traffic accident								
Normal (>=90)	3	(0.3)	3	0.3	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Eye burns								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Eyelid contusion								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Foreign body in eye								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Muscle injury								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Nerve injury						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Post-traumatic pain						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Injury						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bone contusion						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eyelid injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Face injury						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Head injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Ligament injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Musculoskeletal injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Post-traumatic neck syndrome						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skeletal injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Soft tissue foreign body						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Subdural haematoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Tendon injury						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Chest injury						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Corneal abrasion						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eye injury						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gun shot wound						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Post concussion syndrome						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Scar						
Normal (>=90)	0			1	(0.2)	1 0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Tendon rupture						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Bone and joint injuries						
Normal (>=90)	22	(2.5)	25 2.2	11	(2.5)	12 2.1
Mild RI (60-<90)	10	(2.5)	11 2.1	11	(5.5)	11 4.3
Moderate RI (30-<60)	3	(16.7)	3 12.9	0		
Hand fracture						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Stress fracture						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Upper limb fracture						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Joint injury						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Rib fracture						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Meniscus injury						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Foot fracture						
Normal (>=90)	5 (0.6)	7	0.6	1 (0.2)	1	0.2
Mild RI (60-<90)	0			4 (2.0)	4	1.6
Moderate RI (30-<60)	0			0		
Joint dislocation						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Radius fracture						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Facial bones fracture						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Femur fracture						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	1	(0.2)	2	0.4	0			
Moderate RI (30-<60)	0				0			
Spinal compression fracture								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Wrist fracture								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Ankle fracture								
Normal (>=90)	1	(0.1)	1	<0.1	2	(0.4)	2	0.4
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Fractured coccyx								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Thoracic vertebral fracture								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Tibia fracture								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Fibula fracture						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Torus fracture						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Procedural related injuries and complications NEC						
Normal (>=90)	12 (1.4)	14	1.2	3 (0.7)	4	0.7
Mild RI (60-<90)	14 (3.5)	20	3.8	7 (3.5)	8	3.1
Moderate RI (30-<60)	1 (5.6)	1	4.3	1 (10.0)	1	7.5
Post procedural haemorrhage						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Procedural pain						
Normal (>=90)	6 (0.7)	7	0.6	2 (0.4)	3	0.5
Mild RI (60-<90)	6 (1.5)	6	1.1	5 (2.5)	6	2.3
Moderate RI (30-<60)	0			0		
Post procedural complication						
Normal (>=90)	0			0		
Mild RI (60-<90)	4 (1.0)	5	1.0	0		
Moderate RI (30-<60)	0			0		
Injection related reaction						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Procedural nausea						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Administration related reaction						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Anaemia postoperative						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Post procedural constipation						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Procedural haemorrhage						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Urinary retention postoperative						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Anaphylactic transfusion reaction								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Suture related complication								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Vaccination complication								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				1	(10.0)	1	7.5
Procedural vomiting								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Seroma								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Medication errors and other product use errors and issues								
Normal (>=90)	6	(0.7)	6	0.5	1	(0.2)	1	0.2
Mild RI (60-<90)	4	(1.0)	4	0.8	1	(0.5)	2	0.8
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Accidental overdose						
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Medication error						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Incorrect dose administered						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Injuries by physical agents						
Normal (>=90)	3	(0.3)	3 0.3	4	(0.9)	4 0.7
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Sunburn						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Heat exhaustion						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hypobarism						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Heat illness						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Thermal burn						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Burns second degree						
Normal (>=90)	0			3 (0.7)	3	0.5
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Overdoses and underdoses NEC						
Normal (>=90)	3 (0.3)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Overdose						
Normal (>=90)	3 (0.3)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Exposures, chemical injuries and poisoning						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Exposure to toxic agent								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Reactive gastropathy								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Metabolism and nutrition disorders								
Normal (>=90)	134	(15.1)	183	15.8	53	(11.9)	70	12.5
Mild RI (60-<90)	61	(15.2)	70	13.4	26	(13.0)	33	12.8
Moderate RI (30-<60)	4	(22.2)	14	60.3	4	(40.0)	5	37.4
Appetite and general nutritional disorders								
Normal (>=90)	95	(10.7)	121	10.4	21	(4.7)	27	4.8
Mild RI (60-<90)	44	(11.0)	48	9.2	7	(3.5)	9	3.5
Moderate RI (30-<60)	2	(11.1)	3	12.9	0			
Decreased appetite								
Normal (>=90)	84	(9.5)	96	8.3	16	(3.6)	18	3.2
Mild RI (60-<90)	38	(9.5)	40	7.6	6	(3.0)	8	3.1
Moderate RI (30-<60)	2	(11.1)	3	12.9	0			
Food craving								
Normal (>=90)	5	(0.6)	5	0.4	1	(0.2)	1	0.2
Mild RI (60-<90)	3	(0.7)	3	0.6	1	(0.5)	1	0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Increased appetite						
Normal (>=90)	4 (0.5)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Hyperphagia						
Normal (>=90)	6 (0.7)	7	0.6	2 (0.4)	4	0.7
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Food aversion						
Normal (>=90)	3 (0.3)	5	0.4	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Lack of satiety						
Normal (>=90)	2 (0.2)	2	0.2	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Malnutrition						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vitamin related disorders						
Normal (>=90)	12 (1.4)	14	1.2	9 (2.0)	11	2.0
Mild RI (60-<90)	8 (2.0)	8	1.5	0		
Moderate RI (30-<60)	2 (11.1)	6	25.8	1 (10.0)	1	7.5
Vitamin D deficiency						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	8 (0.9)	8	0.7	7 (1.6)	7	1.3
Mild RI (60-<90)	7 (1.7)	7	1.3	0		
Moderate RI (30-<60)	2 (11.1)	2	8.6	1 (10.0)	1	7.5
Vitamin B12 deficiency						
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Folate deficiency						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Vitamin A deficiency						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Vitamin B2 deficiency						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Vitamin B complex deficiency						
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lipid metabolism disorders						
Normal (>=90)	15 (1.7)	16	1.4	10 (2.2)	10	1.8
Mild RI (60-<90)	4 (1.0)	4	0.8	9 (4.5)	10	3.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.6)	1	4.3	1 (10.0)	1	7.5
Hypercholesterolaemia						
Normal (>=90)	2 (0.2)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	2 (0.5)	2	0.4	3 (1.5)	3	1.2
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dyslipidaemia						
Normal (>=90)	9 (1.0)	9	0.8	5 (1.1)	5	0.9
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	4	1.6
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Hypertriglyceridaemia						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Hyperlipidaemia						
Normal (>=90)	0			2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Cholesterosis						
Normal (>=90)	1 (0.1)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Electrolyte and fluid balance conditions						
Normal (>=90)	4 (0.5)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	4 (1.0)	4	0.8	3 (1.5)	3	1.2
Moderate RI (30-<60)	1 (5.6)	3	12.9	1 (10.0)	1	7.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hypokalaemia						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	1	(5.6)	3 12.9	0		
Hyperkalaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Hyponatraemia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Polydipsia						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Dehydration						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Electrolyte imbalance						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Fluid retention						
Normal (>=90)	0			1	(0.2)	1 0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bone, calcium, magnesium and phosphorus metabolism disorders						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hypomagnesaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Glucose metabolism disorders (incl diabetes mellitus)						
Normal (>=90)	8 (0.9)	15	1.3	16 (3.6)	17	3.0
Mild RI (60-<90)	2 (0.5)	2	0.4	4 (2.0)	7	2.7
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Hypoglycaemia						
Normal (>=90)	5 (0.6)	11	0.9	4 (0.9)	5	0.9
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	2	0.8
Moderate RI (30-<60)	0			0		
Glucose tolerance impaired						
Normal (>=90)	1 (0.1)	1	<0.1	3 (0.7)	3	0.5
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Postprandial hypoglycaemia						
Normal (>=90)	1 (0.1)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Type 2 diabetes mellitus						
Normal (>=90)	1	(0.1)	1 <0.1	3	(0.7)	3 0.5
Mild RI (60-<90)	0			2	(1.0)	3 1.2
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Diabetes mellitus						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Hyperglycaemia						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Impaired fasting glucose						
Normal (>=90)	0			3	(0.7)	3 0.5
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Insulin resistance						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Iron and trace metal metabolism disorders						
Normal (>=90)	4	(0.5)	4 0.3	3	(0.7)	3 0.5
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Iron deficiency						
Normal (>=90)	4 (0.5)	4	0.3	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Purine and pyrimidine metabolism disorders						
Normal (>=90)	3 (0.3)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Gout						
Normal (>=90)	3 (0.3)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Hyperuricaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Food intolerance syndromes						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dairy intolerance						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Food intolerance						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lactose intolerance						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Metabolism disorders NEC						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hyperlipasaemia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Protein and amino acid metabolism disorders NEC						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypoalbuminaemia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Skin and subcutaneous tissue disorders						
Normal (>=90)	123 (13.9)	169	14.6	53 (11.9)	69	12.3
Mild RI (60-<90)	61 (15.2)	75	14.3	22 (11.0)	27	10.5
Moderate RI (30-<60)	4 (22.2)	5	21.5	0		
Epidermal and dermal conditions						
Normal (>=90)	69 (7.8)	87	7.5	38 (8.5)	49	8.8
Mild RI (60-<90)	33 (8.2)	39	7.5	14 (7.0)	16	6.2
Moderate RI (30-<60)	3 (16.7)	3	12.9	0		
Pruritus						
Normal (>=90)	13 (1.5)	14	1.2	4 (0.9)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dry skin						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Skin lesion						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Rash						
Normal (>=90)	15 (1.7)	16	1.4	12 (2.7)	18	3.2
Mild RI (60-<90)	11 (2.7)	14	2.7	5 (2.5)	5	1.9
Moderate RI (30-<60)	0			0		
Eczema						
Normal (>=90)	9 (1.0)	9	0.8	4 (0.9)	4	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	4 (1.0)	4	0.8	0		
Moderate RI (30-<60)	0			0		
Dermatitis contact						
Normal (>=90)	1 (0.1)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	4 (1.0)	5	1.0	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Skin burning sensation						
Normal (>=90)	6 (0.7)	12	1.0	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pain of skin						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Blister						
Normal (>=90)	0			4 (0.9)	4	0.7
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Erythema						
Normal (>=90)	2 (0.2)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Psoriasis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Decubitus ulcer						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dermatitis allergic						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dermatitis						
Normal (>=90)	3 (0.3)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Rash pruritic						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin irritation						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Papule						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Perioral dermatitis						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Skin disorder								
Normal (>=90)	2	(0.2)	3	0.3	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Dermatitis atopic								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Macule								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Pityriasis rosea								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Prurigo								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Rash maculo-papular								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Skin discolouration						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Skin odour abnormal						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Xanthelasma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Drug eruption						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Photosensitivity reaction						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Rash erythematous						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Rash macular						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Skin reaction						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin appendage conditions						
Normal (>=90)	58	(6.5)	67 5.8	11	(2.5)	12 2.1
Mild RI (60-<90)	23	(5.7)	24 4.6	8	(4.0)	9 3.5
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Alopecia						
Normal (>=90)	40	(4.5)	42 3.6	3	(0.7)	3 0.5
Mild RI (60-<90)	13	(3.2)	13 2.5	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Hair growth abnormal						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Hyperhidrosis						
Normal (>=90)	6	(0.7)	6 0.5	4	(0.9)	4 0.7
Mild RI (60-<90)	2	(0.5)	2 0.4	4	(2.0)	4 1.6
Moderate RI (30-<60)	0			0		
Acne						
Normal (>=90)	2	(0.2)	2 0.2	2	(0.4)	2 0.4
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hidradenitis						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Cold sweat						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Ingrowing nail						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	2	0.8
Moderate RI (30-<60)	0			0		
Hirsutism						
Normal (>=90)	3 (0.3)	4	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Diffuse alopecia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Nail bed inflammation						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Nail discolouration						
Normal (>=90)	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Miliaria						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Rosacea						
Normal (>=90)	2	(0.2)	3 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Hypertrichosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Night sweats						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Onychoclasis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cornification and dystrophic skin disorders						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	5	(1.2)	7 1.3	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Actinic keratosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	3	0.6	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hyperkeratosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Lichenoid keratosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Skin striae						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Angioedema and urticaria						
Normal (>=90)	11 (1.2)	11	0.9	5 (1.1)	5	0.9
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Urticaria						
Normal (>=90)	10 (1.1)	10	0.9	4 (0.9)	4	0.7
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Cold urticaria						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Angioedema						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pigmentation disorders						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Ephelides						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Skin hyperpigmentation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cutaneous neoplasms benign						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Dermal cyst						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Skin vascular abnormalities								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Ecchymosis								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Skin and subcutaneous tissue disorders NEC								
Normal (>=90)	0				2	(0.4)	2	0.4
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Erythema nodosum								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Skin ulcer								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Vascular disorders								
Normal (>=90)	58	(6.5)	60	5.2	20	(4.5)	22	3.9
Mild RI (60-<90)	27	(6.7)	28	5.4	25	(12.5)	28	10.9

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	5 (27.8)	9	38.7	0		
Decreased and nonspecific blood pressure disorders and shock						
Normal (>=90)	9 (1.0)	9	0.8	1 (0.2)	1	0.2
Mild RI (60-<90)	7 (1.7)	8	1.5	1 (0.5)	1	0.4
Moderate RI (30-<60)	3 (16.7)	4	17.2	0		
Hypotension						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	2 (11.1)	3	12.9	0		
Orthostatic hypotension						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	4 (1.0)	5	1.0	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Circulatory collapse						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vascular hypertensive disorders						
Normal (>=90)	30 (3.4)	30	2.6	13 (2.9)	14	2.5
Mild RI (60-<90)	11 (2.7)	11	2.1	15 (7.5)	18	7.0
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hypertension						
Normal (>=90)	28 (3.2)	28	2.4	13 (2.9)	14	2.5
Mild RI (60-<90)	11 (2.7)	11	2.1	14 (7.0)	17	6.6
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Essential hypertension						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypertensive emergency						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypertensive crisis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Vascular disorders NEC						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	4 (1.0)	4	0.8	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	2	8.6	0		
Hot flush						
Normal (>=90)	4 (0.5)	4	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Flushing						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Vascular haemorrhagic disorders						
Normal (>=90)	4 (0.5)	4	0.3	0		

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RI: Renal impairment
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	4	(2.0)	4 1.6
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Haematoma						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	4	(2.0)	4 1.6
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Embolism and thrombosis						
Normal (>=90)	2	(0.2)	2 0.2	2	(0.4)	2 0.4
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Thrombosis						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Thrombophlebitis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Deep vein thrombosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Thrombophlebitis superficial						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Arteriosclerosis, stenosis, vascular insufficiency and necrosis						
Normal (>=90)	5	(0.6)	5 0.4	3	(0.7)	3 0.5
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Peripheral coldness						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Peripheral venous disease						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Aortic arteriosclerosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Arteriosclerosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Raynaud's phenomenon						
Normal (>=90)	0			3	(0.7)	3 0.5
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Venous varices						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Varicose vein						
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Vascular infections and inflammations						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Arteritis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Phlebitis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lymphatic vessel disorders						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Lymphoedema						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Respiratory, thoracic and mediastinal disorders								
Normal (>=90)	112	(12.6)	146	12.6	67	(15.1)	84	15.0
Mild RI (60-<90)	59	(14.7)	75	14.3	35	(17.5)	48	18.7
Moderate RI (30-<60)	2	(11.1)	4	17.2	2	(20.0)	2	15.0
Upper respiratory tract disorders (excl infections)								
Normal (>=90)	33	(3.7)	34	2.9	10	(2.2)	10	1.8
Mild RI (60-<90)	16	(4.0)	17	3.3	8	(4.0)	11	4.3
Moderate RI (30-<60)	2	(11.1)	2	8.6	0			
Nasal congestion								
Normal (>=90)	8	(0.9)	8	0.7	4	(0.9)	4	0.7
Mild RI (60-<90)	2	(0.5)	2	0.4	2	(1.0)	2	0.8
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Nasal dryness								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Sinus congestion								
Normal (>=90)	7	(0.8)	7	0.6	2	(0.4)	2	0.4
Mild RI (60-<90)	6	(1.5)	6	1.1	3	(1.5)	5	1.9
Moderate RI (30-<60)	0				0			
Rhinitis allergic								
Normal (>=90)	9	(1.0)	9	0.8	3	(0.7)	3	0.5

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	2	(0.5)	2 0.4	3	(1.5)	4 1.6
Moderate RI (30-<60)	0			0		
Epistaxis						
Normal (>=90)	6	(0.7)	6 0.5	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Nasal polyps						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Nasal septum deviation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Paranasal sinus hypersecretion						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Tonsillar hypertrophy						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Vocal cord polyp						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Paranasal cyst						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nasal adhesions						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Respiratory tract signs and symptoms						
Normal (>=90)	52 (5.9)	56	4.8	21 (4.7)	24	4.3
Mild RI (60-<90)	22 (5.5)	24	4.6	12 (6.0)	13	5.1
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Oropharyngeal pain						
Normal (>=90)	32 (3.6)	35	3.0	15 (3.4)	17	3.0
Mild RI (60-<90)	16 (4.0)	18	3.4	8 (4.0)	9	3.5
Moderate RI (30-<60)	0			0		
Upper-airway cough syndrome						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Rhinorrhoea						
Normal (>=90)	4 (0.5)	4	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Upper respiratory tract inflammation						
Normal (>=90)	5 (0.6)	6	0.5	2 (0.4)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Hiccups						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Catarrh						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Diaphragmalgia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Paranasal sinus discomfort						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Dysphonia						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Oropharyngeal discomfort						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pleuritic pain						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Sinus pain						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Yawning						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Upper respiratory tract congestion						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Respiratory disorders NEC						
Normal (>=90)	37 (4.2)	43	3.7	34 (7.6)	39	7.0
Mild RI (60-<90)	23 (5.7)	26	5.0	15 (7.5)	15	5.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	2 (20.0)	2	15.0
Cough						
Normal (>=90)	25 (2.8)	29	2.5	21 (4.7)	23	4.1
Mild RI (60-<90)	14 (3.5)	15	2.9	12 (6.0)	12	4.7
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Dyspnoea						
Normal (>=90)	5 (0.6)	5	0.4	7 (1.6)	7	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Sleep apnoea syndrome						
Normal (>=90)	4	(0.5)	4 0.3	3	(0.7)	3 0.5
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Haemoptysis						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Productive cough						
Normal (>=90)	2	(0.2)	2 0.2	2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Dyspnoea exertional						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Respiratory disorder						
Normal (>=90)	1	(0.1)	1 <0.1	3	(0.7)	3 0.5
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Respiratory tract congestion						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hyperventilation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Acute respiratory failure						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Pulmonary mass						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bronchial disorders (excl neoplasms)						
Normal (>=90)	7	(0.8)	7 0.6	8	(1.8)	9 1.6
Mild RI (60-<90)	7	(1.7)	7 1.3	5	(2.5)	7 2.7
Moderate RI (30-<60)	0			0		
Asthma						
Normal (>=90)	6	(0.7)	6 0.5	5	(1.1)	5 0.9
Mild RI (60-<90)	5	(1.2)	5 1.0	4	(2.0)	6 2.3
Moderate RI (30-<60)	0			0		
Chronic obstructive pulmonary disease						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Wheezing						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Allergic bronchitis						
Normal (>=90)	0			1	(0.2)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lower respiratory tract disorders (excl obstruction and infection)						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Atelectasis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Pulmonary fibrosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pleural disorders						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pleural effusion						
Normal (>=90)	2	(0.2)	2 0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pleurisy						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pulmonary vascular disorders						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Pulmonary embolism						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Investigations						
Normal (>=90)	62 (7.0)	83	7.2	29 (6.5)	37	6.6
Mild RI (60-<90)	28 (7.0)	32	6.1	18 (9.0)	28	10.9
Moderate RI (30-<60)	3 (16.7)	3	12.9	2 (20.0)	2	15.0
Cardiac and vascular investigations (excl enzyme tests)						
Normal (>=90)	6 (0.7)	7	0.6	5 (1.1)	5	0.9
Mild RI (60-<90)	3 (0.7)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	1 (5.6)	1	4.3	1 (10.0)	1	7.5
QRS axis abnormal						
Normal (>=90)	1 (0.1)	1	<0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	1	(5.6)	1	4.3	0			
Heart rate increased								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Blood pressure abnormal								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Electrocardiogram ST segment depression								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Electrocardiogram T wave amplitude decreased								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Blood pressure decreased								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Blood pressure increased								
Normal (>=90)	1	(0.1)	1	<0.1	5	(1.1)	5	0.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Cardiac murmur						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Electrocardiogram T wave inversion						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pulse abnormal						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Electrocardiogram T wave abnormal						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Enzyme investigations NEC						
Normal (>=90)	4	(0.5)	4 0.3	7	(1.6)	7 1.3
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Enzyme level increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood creatine phosphokinase increased						
Normal (>=90)	4 (0.5)	4	0.3	6 (1.3)	6	1.1
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Blood alkaline phosphatase increased						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Haematology investigations (incl blood groups)						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			2 (1.0)	5	1.9
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Haematology test abnormal						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Haemoglobin decreased						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Haematocrit increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Haemoglobin increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Red blood cell count increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Red cell distribution width increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Hepatobiliary investigations						
Normal (>=90)	12 (1.4)	13	1.1	8 (1.8)	10	1.8
Mild RI (60-<90)	4 (1.0)	4	0.8	3 (1.5)	5	1.9
Moderate RI (30-<60)	0			0		
Gamma-glutamyltransferase increased						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Hepatic enzyme increased						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Blood bilirubin increased						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Alanine aminotransferase increased						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Aspartate aminotransferase increased						
Normal (>=90)	1 (0.1)	1	<0.1	3 (0.7)	3	0.5
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Transaminases increased						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal investigations						
Normal (>=90)	10 (1.1)	11	0.9	0		
Mild RI (60-<90)	3 (0.7)	4	0.8	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Lipase increased						
Normal (>=90)	10 (1.1)	10	0.9	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Amylase increased						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Gastric pH						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Pancreatic enzymes increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Protein and chemistry analyses NEC						
Normal (>=90)	10	(1.1)	10 0.9	4	(0.9)	4 0.7
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
C-reactive protein increased						
Normal (>=90)	10	(1.1)	10 0.9	4	(0.9)	4 0.7
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Physical examination and organ system status topics						
Normal (>=90)	4	(0.5)	4 0.3	2	(0.4)	2 0.4
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Weight decreased						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Body mass index decreased						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Respiratory rate increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Weight increased						
Normal (>=90)	2 (0.2)	2	0.2	2 (0.4)	2	0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Body temperature increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	2	0.8
Moderate RI (30-<60)	0			0		
Endocrine investigations (incl sex hormones)						
Normal (>=90)	6 (0.7)	8	0.7	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Blood thyroid stimulating hormone decreased						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Blood calcitonin increased						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Blood thyroid stimulating hormone abnormal						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Thyroxine free increased						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Thyroxine increased						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blood thyroid stimulating hormone increased						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lipid analyses						
Normal (>=90)	8	(0.9)	15 1.3	1	(0.2)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	3	(1.5)	3 1.2
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
High density lipoprotein decreased						
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Blood cholesterol increased						
Normal (>=90)	4 (0.5)	4	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Low density lipoprotein increased						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Lipids increased						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Blood triglycerides increased						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Very low density lipoprotein increased						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Microbiology and serology investigations						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Helicobacter test positive						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Human papilloma virus test positive						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
HIV test positive						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Renal and urinary tract investigations and urinalyses						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
White blood cells urine						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		

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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Blood creatinine increased						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Glomerular filtration rate decreased						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Blood urine present						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cytogenetic investigations						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Prostatic specific antigen increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Metabolic, nutritional and blood gas investigations						
Normal (>=90)	0			3	(0.7)	3 0.5
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Blood glucose increased						

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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Blood uric acid increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Glycosylated haemoglobin increased						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vitamin D decreased						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Reproductive organ and breast investigations (excl hormone analyses)						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Biopsy breast						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Investigations, imaging and histopathology procedures NEC						

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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Smear test						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Precancerous cells present						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Endoscopy						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Water, electrolyte and mineral investigations						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Blood calcium decreased						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blood potassium increased						
Normal (>=90)	1 (0.1)	1	<0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blood iron decreased						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blood sodium increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Serum ferritin decreased						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Musculoskeletal and soft tissue investigations (excl enzyme tests)						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Arthroscopy						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Immunology and allergy investigations						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Antinuclear antibody positive								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Psychiatric disorders								
Normal (>=90)	93	(10.5)	120	10.3	55	(12.4)	78	13.9
Mild RI (60-<90)	29	(7.2)	35	6.7	25	(12.5)	32	12.5
Moderate RI (30-<60)	2	(11.1)	5	21.5	3	(30.0)	3	22.4
Anxiety disorders and symptoms								
Normal (>=90)	36	(4.1)	37	3.2	19	(4.3)	20	3.6
Mild RI (60-<90)	9	(2.2)	10	1.9	10	(5.0)	10	3.9
Moderate RI (30-<60)	1	(5.6)	1	4.3	2	(20.0)	2	15.0
Anxiety								
Normal (>=90)	24	(2.7)	25	2.2	12	(2.7)	12	2.1
Mild RI (60-<90)	7	(1.7)	7	1.3	6	(3.0)	6	2.3
Moderate RI (30-<60)	1	(5.6)	1	4.3	2	(20.0)	2	15.0
Stress								
Normal (>=90)	6	(0.7)	6	0.5	4	(0.9)	4	0.7
Mild RI (60-<90)	2	(0.5)	2	0.4	2	(1.0)	2	0.8
Moderate RI (30-<60)	0				0			
Panic attack								
Normal (>=90)	2	(0.2)	2	0.2	2	(0.4)	2	0.4
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Acute stress disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Burnout syndrome						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nervousness						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Post-traumatic stress disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Agitation						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Generalised anxiety disorder						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Sleep disorders and disturbances						
Normal (>=90)	30	(3.4)	32 2.8	20	(4.5)	23 4.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	9 (2.2)	9	1.7	9 (4.5)	10	3.9
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Insomnia						
Normal (>=90)	21 (2.4)	22	1.9	13 (2.9)	13	2.3
Mild RI (60-<90)	6 (1.5)	6	1.1	5 (2.5)	6	2.3
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Sleep disorder						
Normal (>=90)	5 (0.6)	5	0.4	5 (1.1)	6	1.1
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Initial insomnia						
Normal (>=90)	3 (0.3)	4	0.3	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Middle insomnia						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Nightmare						
Normal (>=90)	0			1 (0.2)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Abnormal dreams						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Sleep terror						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Depressed mood disorders and disturbances						
Normal (>=90)	26 (2.9)	31	2.7	21 (4.7)	23	4.1
Mild RI (60-<90)	6 (1.5)	7	1.3	6 (3.0)	6	2.3
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Major depression						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Depressed mood						
Normal (>=90)	11 (1.2)	12	1.0	6 (1.3)	6	1.1
Mild RI (60-<90)	3 (0.7)	3	0.6	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Depression						
Normal (>=90)	13 (1.5)	14	1.2	13 (2.9)	14	2.5
Mild RI (60-<90)	2 (0.5)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Negative thoughts						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Anhedonia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Tearfulness						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Depressive symptom						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Persistent depressive disorder						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Cognitive and attention disorders and disturbances						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	2 8.6	0		
Mental fatigue						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	2 8.6	0		
Attention deficit/hyperactivity disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Mood disorders and disturbances NEC						
Normal (>=90)	6 (0.7)	6	0.5	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	0			0		
Irritability						
Normal (>=90)	3 (0.3)	3	0.3	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Apathy						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Mood swings						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Affective disorder						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Changes in physical activity						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Restlessness						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Tic						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Sexual dysfunctions, disturbances and gender identity disorders						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Libido decreased						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Libido increased						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Adjustment disorders (incl subtypes)						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	3	(1.5)	3 1.2
Moderate RI (30-<60)	0			1	(10.0)	1 7.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Grief reaction						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Adjustment disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Adjustment disorder with depressed mood						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Suicidal and self-injurious behaviours NEC						
Normal (>=90)	4	(0.5)	4 0.3	2	(0.4)	3 0.5
Mild RI (60-<90)	0			1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Suicidal ideation						
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	2 0.4
Mild RI (60-<90)	0			1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Suicide attempt						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Psychiatric and behavioural symptoms NEC						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Abulia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Psychiatric symptom						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Deliria (incl confusion)						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Disorientation						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Manic and bipolar mood disorders and disturbances						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Bipolar disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Psychiatric disorders NEC						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Alcoholic hangover						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Somatic symptom and related disorders						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Conversion disorder						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blood and lymphatic system disorders						
Normal (>=90)	22	(2.5)	22 1.9	12	(2.7)	17 3.0
Mild RI (60-<90)	10	(2.5)	12 2.3	4	(2.0)	4 1.6
Moderate RI (30-<60)	3	(16.7)	3 12.9	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Anaemias nonhaemolytic and marrow depression						
Normal (>=90)	13 (1.5)	13	1.1	8 (1.8)	9	1.6
Mild RI (60-<90)	8 (2.0)	9	1.7	2 (1.0)	2	0.8
Moderate RI (30-<60)	3 (16.7)	3	12.9	0		
Anaemia						
Normal (>=90)	11 (1.2)	11	0.9	7 (1.6)	8	1.4
Mild RI (60-<90)	7 (1.7)	8	1.5	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Iron deficiency anaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Blood loss anaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hypochromic anaemia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pernicious anaemia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pancytopenia						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Spleen, lymphatic and reticuloendothelial system disorders						
Normal (>=90)	5	(0.6)	5 0.4	3	(0.7)	4 0.7
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Lymphadenopathy						
Normal (>=90)	3	(0.3)	3 0.3	1	(0.2)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hypersplenism						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Splenic haemorrhage						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Splenomegaly						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
White blood cell disorders						
Normal (>=90)	3	(0.3)	3 0.3	0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Leukocytosis						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Eosinophilia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Red blood cell disorders						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Polycythaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Microcytosis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Platelet disorders						
Normal (>=90)	1	(0.1)	1 <0.1	3	(0.7)	3 0.5
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Thrombocytopenia						
Normal (>=90)	1	(0.1)	1 <0.1	3	(0.7)	3 0.5
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Reproductive system and breast disorders						
Normal (>=90)	71	(8.0)	91 7.8	20	(4.5)	26 4.6
Mild RI (60-<90)	24	(6.0)	30 5.7	12	(6.0)	13 5.1
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Breast disorders						
Normal (>=90)	13	(1.5)	15 1.3	3	(0.7)	3 0.5
Mild RI (60-<90)	3	(0.7)	4 0.8	4	(2.0)	5 1.9
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Breast cyst						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Breast mass						
Normal (>=90)	6	(0.7)	6 0.5	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	2 0.8
Moderate RI (30-<60)	0			0		
Fibrocystic breast disease						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Breast disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Breast pain						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Breast inflammation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nipple pain						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Breast fibrosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Breast haematoma						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Menstrual cycle and uterine bleeding disorders						
Normal (>=90)	35	(3.9)	42 3.6	7	(1.6)	10 1.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	10 (2.5)	11	2.1	0		
Moderate RI (30-<60)	0			0		
Menstruation irregular						
Normal (>=90)	9 (1.0)	9	0.8	0		
Mild RI (60-<90)	5 (1.2)	5	1.0	0		
Moderate RI (30-<60)	0			0		
Menorrhagia						
Normal (>=90)	8 (0.9)	10	0.9	3 (0.7)	3	0.5
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Metrorrhagia						
Normal (>=90)	6 (0.7)	6	0.5	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dysmenorrhoea						
Normal (>=90)	7 (0.8)	8	0.7	1 (0.2)	3	0.5
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Menstrual disorder						
Normal (>=90)	4 (0.5)	4	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dysfunctional uterine bleeding						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Oligomenorrhoea						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Amenorrhoea						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Menstruation delayed						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Premenstrual syndrome						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Premenstrual pain						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vulvovaginal disorders (excl infections and inflammations)						
Normal (>=90)	5 (0.6)	5	0.4	2 (0.4)	2	0.4
Mild RI (60-<90)	4 (1.0)	4	0.8	3 (1.5)	3	1.2
Moderate RI (30-<60)	0			0		
Vaginal haemorrhage						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Vulvovaginal discomfort						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Vulvovaginal pain						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Vulvovaginal dryness						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Vaginal polyp						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Vulvovaginal pruritus						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Menopause related conditions						
Normal (>=90)	6	(0.7)	6 0.5	3	(0.7)	4 0.7
Mild RI (60-<90)	3	(0.7)	3 0.6	1	(0.5)	1 0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Atrophic vulvovaginitis						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Menopausal symptoms						
Normal (>=90)	3	(0.3)	3 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Postmenopausal haemorrhage						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ovarian and fallopian tube disorders						
Normal (>=90)	6	(0.7)	6 0.5	3	(0.7)	3 0.5
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Ovarian cyst						
Normal (>=90)	4	(0.5)	4 0.3	2	(0.4)	2 0.4
Mild RI (60-<90)	3	(0.7)	3 0.6	0		
Moderate RI (30-<60)	0			0		
Hydrosalpinx						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Polycystic ovaries						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Uterine, pelvic and broad ligament disorders						
Normal (>=90)	10 (1.1)	10	0.9	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Uterine polyp						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Uterine haemorrhage						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Adenomyosis						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Endometriosis						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Uterine enlargement						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Vaginal prolapse						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cervix disorders (excl infections and inflammations)						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Cervical dysplasia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Cervical leukoplakia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Uterine cervical erosion						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Reproductive tract disorders NEC						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Genital rash								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Pelvic pain								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Genital pain								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Female reproductive tract infections and inflammations								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Uterine inflammation								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Sexual function and fertility disorders								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Dyspareunia								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Erectile dysfunction								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Testicular and epididymal disorders								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Testicular mass								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Testicular pain								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Testicular disorder								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Prostatic disorders (excl infections and inflammations)						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Benign prostatic hyperplasia						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Penile and scrotal disorders (excl infections and inflammations)						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Scrotal pain						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eye disorders						
Normal (>=90)	24 (2.7)	30	2.6	12 (2.7)	16	2.9
Mild RI (60-<90)	18 (4.5)	26	5.0	10 (5.0)	11	4.3
Moderate RI (30-<60)	2 (11.1)	2	8.6	2 (20.0)	4	29.9
Ocular infections, irritations and inflammations						
Normal (>=90)	4 (0.5)	5	0.4	4 (0.9)	5	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	3	(0.7)	4 0.8	2	(1.0)	3 1.2
Moderate RI (30-<60)	1	(5.6)	1 4.3	1	(10.0)	2 15.0
Ocular hyperaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Eye pruritus						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Eye discharge						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Meibomian gland dysfunction						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Swelling of eyelid						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Conjunctival irritation						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Conjunctivitis allergic						
Normal (>=90)	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eczema eyelids						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eye allergy						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Blepharitis						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Conjunctival hyperaemia						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Erythema of eyelid						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Eye inflammation						
Normal (>=90)	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			1	(10.0)	2 15.0
Eye irritation						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Keratitis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ulcerative keratitis						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ocular structural change, deposit and degeneration NEC						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	2	(0.5)	3 0.6	0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Macular degeneration						
Normal (>=90)	0			0		
Mild RI (60-<90)	2	(0.5)	3 0.6	0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Vitreous detachment						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Vision disorders						
Normal (>=90)	9 (1.0)	12	1.0	3 (0.7)	3	0.5
Mild RI (60-<90)	5 (1.2)	5	1.0	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Vision blurred						
Normal (>=90)	5 (0.6)	5	0.4	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Diplopia						
Normal (>=90)	2 (0.2)	3	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Myopia						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Anisometropia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Visual impairment						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Astigmatism						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Photopsia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Scintillating scotoma						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Anterior eye structural change, deposit and degeneration						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	6	(1.5)	7 1.3	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			1	(10.0)	2 15.0
Cataract						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	5	(1.2)	6 1.1	0		
Moderate RI (30-<60)	0			1	(10.0)	2 15.0
Xerophthalmia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Ectropion						
Normal (>=90)	0			1	(0.2)	1 0.2

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pterygium						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Eye disorders NEC						
Normal (>=90)	4	(0.5)	4 0.3	3	(0.7)	3 0.5
Mild RI (60-<90)	4	(1.0)	4 0.8	3	(1.5)	3 1.2
Moderate RI (30-<60)	0			0		
Dry eye						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	3	(0.7)	3 0.6	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Lacrimation increased						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Eyelid disorder						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Eye pain						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Ocular discomfort						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Glaucoma and ocular hypertension						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	2 0.4
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Glaucoma						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	2 0.4
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Ocular haemorrhages and vascular disorders NEC						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Optic ischaemic neuropathy						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Eyelid haematoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Conjunctival haemorrhage						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Retina, choroid and vitreous haemorrhages and vascular disorders						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Retinopathy						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Retinal aneurysm						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Ocular neuromuscular disorders						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Blepharospasm						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Ocular sensory symptoms NEC						
Normal (>=90)	1	(0.1)	1 <0.1	0		

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RI: Renal impairment
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Asthenopia								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Renal and urinary disorders								
Normal (>=90)	29	(3.3)	37	3.2	12	(2.7)	13	2.3
Mild RI (60-<90)	10	(2.5)	10	1.9	9	(4.5)	9	3.5
Moderate RI (30-<60)	2	(11.1)	4	17.2	1	(10.0)	2	15.0
Renal disorders (excl nephropathies)								
Normal (>=90)	3	(0.3)	4	0.3	2	(0.4)	2	0.4
Mild RI (60-<90)	2	(0.5)	2	0.4	4	(2.0)	4	1.6
Moderate RI (30-<60)	2	(11.1)	3	12.9	1	(10.0)	2	15.0
Acute kidney injury								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	2	(11.1)	2	8.6	0			
Chronic kidney disease								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	1	(5.6)	1	4.3	1	(10.0)	1	7.5
Renal cyst								
Normal (>=90)	1	(0.1)	1	<0.1	2	(0.4)	2	0.4
Mild RI (60-<90)	1	(0.2)	1	0.2	2	(1.0)	2	0.8

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Nephrectasia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hydronephrosis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Renal impairment						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Hypertensive nephropathy						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Urinary tract signs and symptoms						
Normal (>=90)	20	(2.3)	23 2.0	6	(1.3)	7 1.3
Mild RI (60-<90)	5	(1.2)	5 1.0	2	(1.0)	2 0.8
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Chromaturia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	0		
Dysuria						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	7 (0.8)	9	0.8	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Stress urinary incontinence						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Haematuria						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Micturition urgency						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Urine odour abnormal						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Pollakiuria						
Normal (>=90)	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Renal pain						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		

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RI: Renal impairment
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Bladder pain						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nocturia						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Renal colic						
Normal (>=90)	1	(0.1)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Urine flow decreased						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Polyuria						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Urinary incontinence						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Urinary retention						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Urolithiases						
Normal (>=90)	8 (0.9)	9	0.8	4 (0.9)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Nephrolithiasis						
Normal (>=90)	5 (0.6)	5	0.4	4 (0.9)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Calculus urinary						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ureterolithiasis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bladder and bladder neck disorders (excl calculi)						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cystitis noninfective						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Urethral disorders (excl calculi)						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Urethritis noninfective						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Cardiac disorders						
Normal (>=90)	24 (2.7)	28	2.4	20 (4.5)	25	4.5
Mild RI (60-<90)	29 (7.2)	32	6.1	12 (6.0)	18	7.0
Moderate RI (30-<60)	1 (5.6)	2	8.6	1 (10.0)	1	7.5
Cardiac arrhythmias						
Normal (>=90)	16 (1.8)	20	1.7	9 (2.0)	11	2.0
Mild RI (60-<90)	15 (3.7)	17	3.3	8 (4.0)	10	3.9
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Atrial fibrillation						
Normal (>=90)	2 (0.2)	5	0.4	3 (0.7)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	0		
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Atrioventricular block first degree						
Normal (>=90)	3 (0.3)	3	0.3	1 (0.2)	1	0.2
Mild RI (60-<90)	2 (0.5)	2	0.4	3 (1.5)	3	1.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Tachycardia						
Normal (>=90)	4 (0.5)	4	0.3	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			0		
Bundle branch block left						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Ventricular extrasystoles						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Atrial flutter						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Atrial tachycardia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Atrioventricular block						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Bradycardia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Cardiac flutter						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Defect conduction intraventricular						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Nodal rhythm						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Arrhythmia						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Sinus tachycardia						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Atrioventricular block second degree						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Bundle branch block right						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Sinus bradycardia						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Supraventricular extrasystoles						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cardiac disorders, signs and symptoms NEC						
Normal (>=90)	2	(0.2)	2 0.2	6	(1.3)	8 1.4
Mild RI (60-<90)	9	(2.2)	9 1.7	1	(0.5)	1 0.4
Moderate RI (30-<60)	1	(5.6)	1 4.3	1	(10.0)	1 7.5
Palpitations						
Normal (>=90)	2	(0.2)	2 0.2	5	(1.1)	7 1.3
Mild RI (60-<90)	7	(1.7)	7 1.3	0		
Moderate RI (30-<60)	1	(5.6)	1 4.3	1	(10.0)	1 7.5
Cardiovascular disorder						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hypertensive heart disease						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Coronary artery disorders						
Normal (>=90)	3 (0.3)	3	0.3	5 (1.1)	5	0.9
Mild RI (60-<90)	4 (1.0)	4	0.8	2 (1.0)	3	1.2
Moderate RI (30-<60)	0			0		
Acute myocardial infarction						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Angina pectoris						
Normal (>=90)	1 (0.1)	1	<0.1	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Angina unstable						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Coronary artery stenosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Arteriosclerosis coronary artery						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Coronary artery disease								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Myocardial infarction								
Normal (>=90)	0				2	(0.4)	2	0.4
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Cardiac valve disorders								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	1	(0.2)	1	0.2	1	(0.5)	2	0.8
Moderate RI (30-<60)	0				0			
Aortic valve incompetence								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Aortic valve sclerosis								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Mitral valve incompetence								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Tricuspid valve incompetence								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Cardiac neoplasms								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Pericardial cyst								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Myocardial disorders								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				2	(1.0)	2	0.8
Moderate RI (30-<60)	0				0			
Left ventricular hypertrophy								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Cardiomegaly								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Cardiomyopathy								
Normal (>=90)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Myocarditis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Pericardial disorders						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pericardial disease						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Endocrine disorders						
Normal (>=90)	10 (1.1)	12	1.0	4 (0.9)	5	0.9
Mild RI (60-<90)	3 (0.7)	3	0.6	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Thyroid gland disorders						
Normal (>=90)	9 (1.0)	11	0.9	4 (0.9)	4	0.7
Mild RI (60-<90)	3 (0.7)	3	0.6	2 (1.0)	2	0.8
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hypothyroidism						
Normal (>=90)	2 (0.2)	2	0.2	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.6)	1	4.3	0		
Hyperthyroidism						
Normal (>=90)	2 (0.2)	3	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Thyroid mass						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Goitre						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Thyroid cyst						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Primary hyperthyroidism						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Adrenal gland disorders						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hyperadrenocorticism						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Endocrine disorders of gonadal function						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypogonadism						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Normal (>=90)	30	(3.4)	30 2.6	9	(2.0)	9 1.6
Mild RI (60-<90)	16	(4.0)	22 4.2	15	(7.5)	17 6.6
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Cutaneous neoplasms benign						
Normal (>=90)	5	(0.6)	5 0.4	1	(0.2)	1 0.2
Mild RI (60-<90)	5	(1.2)	9 1.7	5	(2.5)	5 1.9
Moderate RI (30-<60)	0			0		
Melanocytic naevus						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	5	(1.2)	6 1.1	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Acrochordon						
Normal (>=90)	0			0		
Mild RI (60-<90)	2 (0.5)	2	0.4	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Seborrhoeic keratosis						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Dysplastic naevus						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin papilloma						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Pyogenic granuloma						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Reproductive neoplasms female benign						
Normal (>=90)	5 (0.6)	5	0.4	3 (0.7)	3	0.5
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Uterine leiomyoma						
Normal (>=90)	4 (0.5)	4	0.3	3 (0.7)	3	0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Ovarian adenoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Breast neoplasms malignant and unspecified (incl nipple)						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Intraductal proliferative breast lesion						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Invasive ductal breast carcinoma						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Breast cancer						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lobular breast carcinoma in situ						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Phyllodes tumour						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Soft tissue neoplasms benign						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Lipoma						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	1	(0.5)	1 0.4
Moderate RI (30-<60)	0			1	(10.0)	1 7.5
Leiomyoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal neoplasms benign						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Colon adenoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Skin neoplasms malignant and unspecified						
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Basal cell carcinoma						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Malignant melanoma						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Malignant melanoma in situ						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Neoplasm skin						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Breast neoplasms benign (incl nipple)						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Benign breast neoplasm						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.1)	1	<0.1	2 (0.4)	2	0.4
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Endocrine neoplasms benign						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Benign neoplasm of thyroid gland						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Parathyroid tumour benign						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Miscellaneous and site unspecified neoplasms malignant and unspecified						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Squamous cell carcinoma						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Neoplasm						
Normal (>=90)	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Endocrine neoplasms malignant and unspecified								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Papillary thyroid cancer								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Gastrointestinal neoplasms malignant and unspecified								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Gastrointestinal stromal tumour								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Reproductive neoplasms male malignant and unspecified								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Prostate cancer								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Soft tissue neoplasms malignant and unspecified								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Dermatofibrosarcoma protuberans								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Hepatic and biliary neoplasms benign								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Haemangioma of liver								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Hepatobiliary neoplasms malignant and unspecified								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Hepatic neoplasm								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Miscellaneous and site unspecified neoplasms benign								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Fibroma								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Adenoma benign								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Reproductive neoplasms female malignant and unspecified								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Cervix carcinoma stage 0								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Skeletal neoplasms benign								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Haemangioma of bone						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Leukaemias						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hairy cell leukaemia						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Nervous system neoplasms malignant and unspecified NEC						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Glioblastoma						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Ocular neoplasms						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Eyelid haemangioma						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Plasma cell neoplasms						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Paraproteinaemia						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Renal and urinary tract neoplasms benign						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Kidney angiomyolipoma						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Renal and urinary tract neoplasms malignant and unspecified						
Normal (>=90)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Urinary tract neoplasm						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Hepatobiliary disorders						
Normal (>=90)	33 (3.7)	43	3.7	8 (1.8)	8	1.4
Mild RI (60-<90)	11 (2.7)	13	2.5	5 (2.5)	6	2.3
Moderate RI (30-<60)	0			0		
Gallbladder disorders						
Normal (>=90)	24 (2.7)	30	2.6	4 (0.9)	4	0.7
Mild RI (60-<90)	7 (1.7)	8	1.5	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Cholelithiasis						
Normal (>=90)	20 (2.3)	21	1.8	3 (0.7)	3	0.5
Mild RI (60-<90)	3 (0.7)	3	0.6	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Gallbladder disorder						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	2 (0.5)	2	0.4	0		
Moderate RI (30-<60)	0			0		
Cholecystitis acute						
Normal (>=90)	3 (0.3)	3	0.3	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Cholecystitis						
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Cholecystitis chronic						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Biliary dyskinesia						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hepatic and hepatobiliary disorders						
Normal (>=90)	9	(1.0)	12 1.0	4	(0.9)	4 0.7
Mild RI (60-<90)	4	(1.0)	4 0.8	5	(2.5)	5 1.9
Moderate RI (30-<60)	0			0		
Hepatic steatosis						
Normal (>=90)	4	(0.5)	4 0.3	4	(0.9)	4 0.7
Mild RI (60-<90)	2	(0.5)	2 0.4	3	(1.5)	3 1.2
Moderate RI (30-<60)	0			0		
Hepatic function abnormal						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Nonalcoholic fatty liver disease						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Hepatic cyst						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Granulomatous liver disease						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hepatic pain						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypertransaminasaemia						
Normal (>=90)	1	(0.1)	3 0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Portal vein thrombosis						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Bile duct disorders						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Bile duct stone						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Biliary colic						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ear and labyrinth disorders						
Normal (>=90)	35	(3.9)	45 3.9	13	(2.9)	16 2.9
Mild RI (60-<90)	10	(2.5)	11 2.1	11	(5.5)	13 5.1
Moderate RI (30-<60)	0			0		
Inner ear and VIIIth cranial nerve disorders						
Normal (>=90)	19	(2.1)	23 2.0	10	(2.2)	12 2.1
Mild RI (60-<90)	3	(0.7)	3 0.6	8	(4.0)	10 3.9
Moderate RI (30-<60)	0			0		
Vertigo						
Normal (>=90)	14	(1.6)	14 1.2	6	(1.3)	6 1.1
Mild RI (60-<90)	3	(0.7)	3 0.6	6	(3.0)	7 2.7
Moderate RI (30-<60)	0			0		
Tinnitus						
Normal (>=90)	3	(0.3)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	2 0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Vertigo positional						
Normal (>=90)	3	(0.3)	4 0.3	2	(0.4)	3 0.5
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Meniere's disease						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Motion sickness						
Normal (>=90)	0			1	(0.2)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Aural disorders NEC						
Normal (>=90)	11	(1.2)	11 0.9	2	(0.4)	2 0.4
Mild RI (60-<90)	4	(1.0)	5 1.0	0		
Moderate RI (30-<60)	0			0		
Ear pain						
Normal (>=90)	9	(1.0)	9 0.8	2	(0.4)	2 0.4
Mild RI (60-<90)	3	(0.7)	4 0.8	0		
Moderate RI (30-<60)	0			0		
Ear discomfort						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Ear congestion						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Middle ear disorders (excl congenital)						
Normal (>=90)	5	(0.6)	6 0.5	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	2	(1.0)	2 0.8
Moderate RI (30-<60)	0			0		
Eustachian tube dysfunction						
Normal (>=90)	4	(0.5)	5 0.4	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Eustachian tube disorder						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Tympanic membrane disorder						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
External ear disorders (excl congenital)						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Cerumen impaction						
Normal (>=90)	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	2	(0.5)	2 0.4	0		
Moderate RI (30-<60)	0			0		
Excessive cerumen production						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hearing disorders						
Normal (>=90)	4	(0.5)	4 0.3	1	(0.2)	1 0.2
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Deafness neurosensory						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hypoacusis						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Sudden hearing loss						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Deafness						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hyperacusis						
Normal (>=90)	0			1 (0.2)	1	0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Immune system disorders						
Normal (>=90)	18 (2.0)	18	1.6	12 (2.7)	12	2.1
Mild RI (60-<90)	10 (2.5)	10	1.9	9 (4.5)	11	4.3
Moderate RI (30-<60)	0			0		
Allergic conditions						
Normal (>=90)	18 (2.0)	18	1.6	12 (2.7)	12	2.1
Mild RI (60-<90)	9 (2.2)	9	1.7	9 (4.5)	11	4.3
Moderate RI (30-<60)	0			0		
Seasonal allergy						
Normal (>=90)	9 (1.0)	9	0.8	6 (1.3)	6	1.1
Mild RI (60-<90)	6 (1.5)	6	1.1	8 (4.0)	8	3.1
Moderate RI (30-<60)	0			0		
Allergy to arthropod bite						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Food allergy						
Normal (>=90)	1 (0.1)	1	<0.1	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Hypersensitivity						

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	3	(0.3)	3	0.3	3	(0.7)	3	0.5
Mild RI (60-<90)	0				3	(1.5)	3	1.2
Moderate RI (30-<60)	0				0			
Rubber sensitivity								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			
Drug hypersensitivity								
Normal (>=90)	2	(0.2)	2	0.2	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Allergy to arthropod sting								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Mite allergy								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Multiple allergies								
Normal (>=90)	0				1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Immune disorders NEC								
Normal (>=90)	0				0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0		
Immunisation reaction						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Surgical and medical procedures						
Normal (>=90)	12 (1.4)	13	1.1	5 (1.1)	5	0.9
Mild RI (60-<90)	6 (1.5)	6	1.1	2 (1.0)	2	0.8
Moderate RI (30-<60)	0			1 (10.0)	1	7.5
Head and neck therapeutic procedures						
Normal (>=90)	5 (0.6)	5	0.4	0		
Mild RI (60-<90)	1 (0.2)	1	0.2	1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Sinus operation						
Normal (>=90)	0			0		
Mild RI (60-<90)	1 (0.2)	1	0.2	0		
Moderate RI (30-<60)	0			0		
Dental operation						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			1 (0.5)	1	0.4
Moderate RI (30-<60)	0			0		
Tooth extraction						
Normal (>=90)	2 (0.2)	2	0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Dental implantation								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Therapeutic procedures and supportive care NEC								
Normal (>=90)	2	(0.2)	2	0.2	0			
Mild RI (60-<90)	2	(0.5)	2	0.4	0			
Moderate RI (30-<60)	0				1	(10.0)	1	7.5
Polypectomy								
Normal (>=90)	0				0			
Mild RI (60-<90)	2	(0.5)	2	0.4	0			
Moderate RI (30-<60)	0				1	(10.0)	1	7.5
Cyst removal								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Spinal anaesthesia								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Skin and subcutaneous tissue therapeutic procedures								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	1	(0.2)	1	0.2	0			
Moderate RI (30-<60)	0				0			

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Skin neoplasm excision						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Acrochordon excision						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bone and joint therapeutic procedures						
Normal (>=90)	0			2	(0.4)	2 0.4
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Synovial cyst removal						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Bone prosthesis insertion						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Hip surgery						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Soft tissue therapeutic procedures						
Normal (>=90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Lipoma excision						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Eye therapeutic procedures						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Glaucoma surgery						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastrointestinal therapeutic procedures						
Normal (>=90)	1	(0.1)	1 <0.1	2	(0.4)	2 0.4
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gastric bypass						
Normal (>=90)	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Abdominoplasty						
Normal (>=90)	0			1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Hepatobiliary therapeutic procedures								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Cholecystectomy								
Normal (>=90)	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Nervous system, skull and spine therapeutic procedures								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Intervertebral disc operation								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Obstetric and gynaecological therapeutic procedures								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Abortion induced								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0		
Ovarian operation						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		
Social circumstances						
Normal (>=90)	5	(0.6)	5 0.4	1	(0.2)	1 0.2
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Age related factors						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Menopause						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Economic and housing issues						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Stress at work						
Normal (>=90)	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Family issues						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Family stress						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Lifestyle issues						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Bedridden						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Pregnancy, puerperium and perinatal conditions						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Abortions and stillbirth						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Abortion						
Normal (>=90)	0			0		
Mild RI (60-<90)	1	(0.2)	1 0.2	0		
Moderate RI (30-<60)	0			0		
Abortion spontaneous						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Maternal complications of pregnancy						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Ectopic pregnancy						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Morning sickness						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Congenital, familial and genetic disorders						
Normal (>=90)	4	(0.5)	4 0.3	0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4
Moderate RI (30-<60)	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Metabolic and nutritional disorders congenital						
Normal (>=90)	3	(0.3)	3 0.3	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Type V hyperlipidaemia						
Normal (>=90)	2	(0.2)	2 0.2	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Gilbert's syndrome						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Musculoskeletal and connective tissue disorders congenital						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Carpus curvus						
Normal (>=90)	1	(0.1)	1 <0.1	0		
Mild RI (60-<90)	0			0		
Moderate RI (30-<60)	0			0		
Skin and subcutaneous tissue disorders congenital						
Normal (>=90)	0			0		
Mild RI (60-<90)	0			1	(0.5)	1 0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0			
Dermoid cyst								
Normal (>=90)	0				0			
Mild RI (60-<90)	0				1	(0.5)	1	0.4
Moderate RI (30-<60)	0				0			
Product issues								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Device issues								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			
Device expulsion								
Normal (>=90)	1	(0.1)	1	<0.1	0			
Mild RI (60-<90)	0				0			
Moderate RI (30-<60)	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

27 Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Normal (>=90)	265	350.8			270	364.2			259	346.0		
Mild RI (60-<90)	120	157.2			114	149.3			120	153.9		
Moderate RI (30-<60)	17	21.8			18	18.1			23	28.4		
Severe RI (15-<30)					1	1.4						
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Normal (>=90)	216	(81.5)	1218	347.2	233	(86.3)	1293	355.1	196	(75.7)	833	240.7
Mild RI (60-<90)	100	(83.3)	561	356.9	103	(90.4)	787	527.1	96	(80.0)	443	287.9
Moderate RI (30-<60)	13	(76.5)	80	366.4	16	(88.9)	115	633.7	17	(73.9)	112	394.1
Severe RI (15-<30)					1	(100)	2	140.8				
Serious												
Yes												
Normal (>=90)	17	(6.4)	29	8.3	22	(8.1)	25	6.9	22	(8.5)	30	8.7
Mild RI (60-<90)	14	(11.7)	24	15.3	12	(10.5)	24	16.1	10	(8.3)	17	11.0
Moderate RI (30-<60)	0				6	(33.3)	22	121.2	5	(21.7)	6	21.1
Severe RI (15-<30)					0							
No												
Normal (>=90)	214	(80.8)	1189	339.0	233	(86.3)	1268	348.2	195	(75.3)	803	232.1
Mild RI (60-<90)	99	(82.5)	537	341.6	103	(90.4)	763	511.0	95	(79.2)	426	276.8
Moderate RI (30-<60)	13	(76.5)	80	366.4	15	(83.3)	93	512.5	17	(73.9)	106	373.0
Severe RI (15-<30)					1	(100)	2	140.8				

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severity												
Severe												
Normal (>=90)	10	(3.8)	24	6.8	13	(4.8)	16	4.4	18	(6.9)	23	6.6
Mild RI (60-<90)	12	(10.0)	19	12.1	10	(8.8)	15	10.0	7	(5.8)	12	7.8
Moderate RI (30-<60)	0				4	(22.2)	20	110.2	3	(13.0)	4	14.1
Severe RI (15-<30)					0							
Moderate												
Normal (>=90)	91	(34.3)	198	56.4	104	(38.5)	292	80.2	63	(24.3)	145	41.9
Mild RI (60-<90)	38	(31.7)	108	68.7	57	(50.0)	185	123.9	45	(37.5)	95	61.7
Moderate RI (30-<60)	6	(35.3)	9	41.2	12	(66.7)	31	170.8	10	(43.5)	24	84.5
Severe RI (15-<30)					0							
Mild												
Normal (>=90)	201	(75.8)	996	284.0	214	(79.3)	985	270.5	179	(69.1)	665	192.2
Mild RI (60-<90)	93	(77.5)	434	276.1	100	(87.7)	587	393.1	84	(70.0)	336	218.3
Moderate RI (30-<60)	12	(70.6)	71	325.2	13	(72.2)	64	352.7	16	(69.6)	84	295.6
Severe RI (15-<30)					1	(100)	2	140.8				
Relationship to trial product												
Missing												
Normal (>=90)	5	(1.9)	5	1.4	5	(1.9)	5	1.4	4	(1.5)	5	1.4
Mild RI (60-<90)	4	(3.3)	4	2.5	5	(4.4)	5	3.3	2	(1.7)	2	1.3
Moderate RI (30-<60)	1	(5.9)	2	9.2	0				0			
Severe RI (15-<30)					0							
Probable												
Normal (>=90)	95	(35.8)	261	74.4	108	(40.0)	269	73.9	43	(16.6)	75	21.7
Mild RI (60-<90)	33	(27.5)	77	49.0	54	(47.4)	176	117.9	15	(12.5)	18	11.7
Moderate RI (30-<60)	5	(29.4)	6	27.5	7	(38.9)	11	60.6	4	(17.4)	7	24.6
Severe RI (15-<30)					0							

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Possible									
Normal (>=90)	89 (33.6)	248	70.7	119 (44.1)	324	89.0	52 (20.1)	95	27.5
Mild RI (60-<90)	55 (45.8)	138	87.8	56 (49.1)	178	119.2	33 (27.5)	57	37.0
Moderate RI (30-<60)	9 (52.9)	21	96.2	7 (38.9)	32	176.3	8 (34.8)	18	63.3
Severe RI (15-<30)				0					
Unlikely									
Normal (>=90)	191 (72.1)	704	200.7	195 (72.2)	695	190.8	182 (70.3)	658	190.2
Mild RI (60-<90)	94 (78.3)	342	217.6	90 (78.9)	428	286.6	91 (75.8)	366	237.8
Moderate RI (30-<60)	11 (64.7)	51	233.6	15 (83.3)	72	396.8	16 (69.6)	87	306.1
Severe RI (15-<30)				1 (100)	2	140.8			
Outcome									
Fatal									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0					
Recovered									
Normal (>=90)	206 (77.7)	1002	285.7	220 (81.5)	1110	304.8	180 (69.5)	642	185.5
Mild RI (60-<90)	96 (80.0)	440	279.9	97 (85.1)	613	410.6	90 (75.0)	328	213.1
Moderate RI (30-<60)	13 (76.5)	61	279.4	15 (83.3)	88	484.9	15 (65.2)	84	295.6
Severe RI (15-<30)				1 (100)	1	70.4			
Recovering									
Normal (>=90)	13 (4.9)	18	5.1	12 (4.4)	18	4.9	12 (4.6)	12	3.5
Mild RI (60-<90)	5 (4.2)	6	3.8	4 (3.5)	7	4.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	1 (5.9)	8	36.6	1 (5.6)	1	5.5	2 (8.7)	4	14.1
Severe RI (15-<30)				0					

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Outcome									
Recovered With Sequelae									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	3	0.8	1 (0.4)	1	0.3
Mild RI (60-<90)	3 (2.5)	3	1.9	0			0		
Moderate RI (30-<60)	0			2 (11.1)	2	11.0	0		
Severe RI (15-<30)				0					
Not Recovered									
Normal (>=90)	92 (34.7)	196	55.9	93 (34.4)	155	42.6	97 (37.5)	174	50.3
Mild RI (60-<90)	50 (41.7)	112	71.3	60 (52.6)	167	111.8	50 (41.7)	112	72.8
Moderate RI (30-<60)	5 (29.4)	11	50.4	9 (50.0)	22	121.2	9 (39.1)	24	84.5
Severe RI (15-<30)				1 (100)	1	70.4			
Unknown									
Normal (>=90)	0			3 (1.1)	7	1.9	3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0					
Leading to									
Permanent treatment discontinuation									
Normal (>=90)	10 (3.8)	11	3.1	10 (3.7)	14	3.8	9 (3.5)	13	3.8
Mild RI (60-<90)	10 (8.3)	12	7.6	10 (8.8)	15	10.0	5 (4.2)	5	3.2
Moderate RI (30-<60)	0			5 (27.8)	5	27.6	0		
Severe RI (15-<30)				0					
Temporary interruption of trial product									
Normal (>=90)	16 (6.0)	33	9.4	22 (8.1)	43	11.8	10 (3.9)	14	4.0
Mild RI (60-<90)	10 (8.3)	14	8.9	12 (10.5)	29	19.4	4 (3.3)	4	2.6
Moderate RI (30-<60)	0			3 (16.7)	18	99.2	1 (4.3)	2	7.0
Severe RI (15-<30)				0					

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Leading to												
Dose reduction of trial product												
Normal (>=90)	9	(3.4)	15	4.3	23	(8.5)	46	12.6	3	(1.2)	3	0.9
Mild RI (60-<90)	9	(7.5)	13	8.3	11	(9.6)	19	12.7	0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0							

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

28 Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Normal (>=90)	265		350.8		270		364.2		259		346.0	
Mild RI (60-<90)	120		157.2		114		149.3		120		153.9	
Moderate RI (30-<60)	17		21.8		18		18.1		23		28.4	
Severe RI (15-<30)					1		1.4		0			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Normal (>=90)	216	(81.5)	1218	347.2	233	(86.3)	1293	355.1	196	(75.7)	833	240.7
Mild RI (60-<90)	100	(83.3)	561	356.9	103	(90.4)	787	527.1	96	(80.0)	443	287.9
Moderate RI (30-<60)	13	(76.5)	80	366.4	16	(88.9)	115	633.7	17	(73.9)	112	394.1
Severe RI (15-<30)					1	(100)	2	140.8	0			
Gastrointestinal disorders												
Normal (>=90)	150	(56.6)	480	136.8	164	(60.7)	548	150.5	92	(35.5)	175	50.6
Mild RI (60-<90)	72	(60.0)	211	134.2	80	(70.2)	342	229.1	38	(31.7)	68	44.2
Moderate RI (30-<60)	9	(52.9)	33	151.1	12	(66.7)	34	187.4	8	(34.8)	19	66.9
Severe RI (15-<30)					0				0			
Gastrointestinal signs and symptoms												
Normal (>=90)	120	(45.3)	292	83.2	129	(47.8)	352	96.7	47	(18.1)	77	22.3
Mild RI (60-<90)	59	(49.2)	128	81.4	61	(53.5)	231	154.7	25	(20.8)	31	20.1
Moderate RI (30-<60)	8	(47.1)	12	55.0	10	(55.6)	18	99.2	4	(17.4)	7	24.6
Severe RI (15-<30)					0				0			
Nausea												
Normal (>=90)	87	(32.8)	138	39.3	87	(32.2)	146	40.1	22	(8.5)	28	8.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	38 (31.7)	54	34.4	44 (38.6)	98	65.6	12 (10.0)	13	8.4
Moderate RI (30-<60)	4 (23.5)	6	27.5	5 (27.8)	5	27.6	3 (13.0)	4	14.1
Severe RI (15-<30)				0			0		
Vomiting									
Normal (>=90)	37 (14.0)	64	18.2	59 (21.9)	102	28.0	8 (3.1)	9	2.6
Mild RI (60-<90)	15 (12.5)	26	16.5	26 (22.8)	80	53.6	2 (1.7)	2	1.3
Moderate RI (30-<60)	2 (11.8)	3	13.7	3 (16.7)	6	33.1	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Dyspepsia									
Normal (>=90)	13 (4.9)	13	3.7	15 (5.6)	18	4.9	4 (1.5)	4	1.2
Mild RI (60-<90)	14 (11.7)	14	8.9	7 (6.1)	8	5.4	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			3 (16.7)	4	22.0	0		
Severe RI (15-<30)				0			0		
Flatulence									
Normal (>=90)	15 (5.7)	18	5.1	7 (2.6)	8	2.2	4 (1.5)	6	1.7
Mild RI (60-<90)	6 (5.0)	7	4.5	8 (7.0)	12	8.0	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Abdominal pain									
Normal (>=90)	12 (4.5)	15	4.3	8 (3.0)	8	2.2	3 (1.2)	3	0.9
Mild RI (60-<90)	5 (4.2)	5	3.2	4 (3.5)	6	4.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Abdominal discomfort									
Normal (>=90)	6 (2.3)	7	2.0	9 (3.3)	11	3.0	3 (1.2)	3	0.9
Mild RI (60-<90)	7 (5.8)	8	5.1	3 (2.6)	3	2.0	4 (3.3)	4	2.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	2 (11.8)	2	9.2	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Abdominal distension									
Normal (>=90)	6 (2.3)	8	2.3	19 (7.0)	23	6.3	9 (3.5)	11	3.2
Mild RI (60-<90)	3 (2.5)	4	2.5	5 (4.4)	7	4.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eructation									
Normal (>=90)	7 (2.6)	10	2.9	9 (3.3)	13	3.6	0		
Mild RI (60-<90)	3 (2.5)	5	3.2	7 (6.1)	8	5.4	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Abdominal pain upper									
Normal (>=90)	9 (3.4)	9	2.6	11 (4.1)	13	3.6	9 (3.5)	10	2.9
Mild RI (60-<90)	2 (1.7)	2	1.3	5 (4.4)	8	5.4	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	2	7.0
Severe RI (15-<30)				0			0		
Abdominal pain lower									
Normal (>=90)	3 (1.1)	3	0.9	3 (1.1)	3	0.8	3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Regurgitation									
Normal (>=90)	0			3 (1.1)	3	0.8	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Gastrointestinal sounds abnormal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abnormal faeces									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aerophagia									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Epigastric discomfort									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal pain									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Abdominal rigidity									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Anal incontinence									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Breath odour									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dysphagia									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Faeces discoloured									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Faeces soft									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (0.8)	2	0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retching									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal motility and defaecation conditions									
Normal (>=90)	80 (30.2)	156	44.5	86 (31.9)	145	39.8	47 (18.1)	68	19.7
Mild RI (60-<90)	39 (32.5)	69	43.9	49 (43.0)	81	54.2	16 (13.3)	22	14.3
Moderate RI (30-<60)	6 (35.3)	18	82.4	8 (44.4)	13	71.6	7 (30.4)	11	38.7
Severe RI (15-<30)				0			0		
Diarrhoea									
Normal (>=90)	59 (22.3)	105	29.9	58 (21.5)	95	26.1	29 (11.2)	42	12.1
Mild RI (60-<90)	26 (21.7)	40	25.4	24 (21.1)	41	27.5	13 (10.8)	16	10.4
Moderate RI (30-<60)	4 (23.5)	13	59.5	4 (22.2)	5	27.6	6 (26.1)	8	28.2
Severe RI (15-<30)				0			0		
Constipation									
Normal (>=90)	30 (11.3)	43	12.3	38 (14.1)	45	12.4	15 (5.8)	19	5.5
Mild RI (60-<90)	18 (15.0)	23	14.6	28 (24.6)	31	20.8	4 (3.3)	4	2.6
Moderate RI (30-<60)	3 (17.6)	4	18.3	4 (22.2)	6	33.1	3 (13.0)	3	10.6
Severe RI (15-<30)				0			0		
Gastrooesophageal reflux disease									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	7 (2.6)	7	2.0	3 (1.1)	3	0.8	6 (2.3)	6	1.7
Mild RI (60-<90)	5 (4.2)	6	3.8	7 (6.1)	8	5.4	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	2	11.0	0		
Severe RI (15-<30)				0			0		
Change of bowel habit									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal motility disorder									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Irritable bowel syndrome									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal hypermotility									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrooesophageal sphincter insufficiency									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal inflammatory conditions									
Normal (>=90)	5 (1.9)	5	1.4	11 (4.1)	12	3.3	4 (1.5)	5	1.4
Mild RI (60-<90)	3 (2.5)	3	1.9	5 (4.4)	7	4.7	2 (1.7)	3	1.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Gastritis									
Normal (>=90)	4 (1.5)	4	1.1	8 (3.0)	9	2.5	3 (1.2)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	3	2.0	1 (0.8)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Enteritis									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Enterocolitis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chronic gastritis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Duodenitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Colitis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal conditions NEC									
Normal (>=90)	6 (2.3)	7	2.0	16 (5.9)	19	5.2	4 (1.5)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Gastrointestinal disorder									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hyperchlorhydria									
Normal (>=90)	4 (1.5)	5	1.4	11 (4.1)	14	3.8	2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Food poisoning									
Normal (>=90)	2 (0.8)	2	0.6	4 (1.5)	4	1.1	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Barrett's oesophagus									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastric disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal melanosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dental and gingival conditions									
Normal (>=90)	7 (2.6)	8	2.3	6 (2.2)	7	1.9	5 (1.9)	5	1.4
Mild RI (60-<90)	0			4 (3.5)	4	2.7	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Toothache									
Normal (>=90)	4 (1.5)	5	1.4	4 (1.5)	4	1.1	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dental caries									
Normal (>=90)	1 (0.4)	1	0.3	3 (1.1)	3	0.8	5 (1.9)	5	1.4
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Gingival swelling									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tooth deposit									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Periodontal disease									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Exocrine pancreas conditions												
Normal (>=90)	1	(0.4)	1	0.3	0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Pancreatitis acute												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Obstructive pancreatitis												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Pancreatic cyst												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Gastrointestinal vascular conditions												
Normal (>=90)	1	(0.4)	2	0.6	5	(1.9)	5	1.4	1	(0.4)	1	0.3
Mild RI (60-<90)	2	(1.7)	3	1.9	4	(3.5)	4	2.7	1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Haemorrhoids									
Normal (>=90)	1 (0.4)	2	0.6	5 (1.9)	5	1.4	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	4 (3.5)	4	2.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haemorrhoids thrombosed									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Varices oesophageal									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abdominal hernias and other abdominal wall conditions									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	0			3 (2.6)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abdominal hernia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hiatus hernia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Umbilical hernia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abdominal wall haematoma									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Inguinal hernia									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal haemorrhages NEC									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	3	2.0	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Haematochezia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Intra-abdominal haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Upper gastrointestinal haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mallory-Weiss syndrome									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Intra-abdominal haematoma									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rectal haemorrhage									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Benign neoplasms gastrointestinal									
Normal (>=90)	2 (0.8)	2	0.6	0			4 (1.5)	4	1.2
Mild RI (60-<90)	3 (2.5)	4	2.5	3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastric polyps									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Large intestine polyp									
Normal (>=90)	2 (0.8)	2	0.6	0			2 (0.8)	2	0.6
Mild RI (60-<90)	2 (1.7)	2	1.3	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Salivary gland conditions									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dry mouth									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Parotid gland enlargement									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Salivary hypersecretion									
Normal (>=90)	0			1	(0.4)	2 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Noninfective sialoadenitis									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Oral soft tissue conditions									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			2	(1.8)	2 1.3	1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Mouth ulceration									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Stomatitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aphthous ulcer									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lip swelling									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Odynophagia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diverticular disorders									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	2	(1.7)	2 1.3	1	(0.9)	1 0.7	1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diverticulum intestinal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diverticulum									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal ulceration and perforation									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastritis erosive									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diverticular perforation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Gastric ulcer												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Anal and rectal conditions NEC												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Anal fissure												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Gastrointestinal stenosis and obstruction												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Small intestinal obstruction												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Malabsorption conditions									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Malabsorption									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peritoneal and retroperitoneal conditions									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retroperitoneal mass									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tongue conditions									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Glossodynia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Musculoskeletal and connective tissue disorders									
Normal (>=90)	71 (26.8)	109	31.1	56 (20.7)	80	22.0	44 (17.0)	61	17.6
Mild RI (60-<90)	23 (19.2)	30	19.1	37 (32.5)	62	41.5	31 (25.8)	49	31.8
Moderate RI (30-<60)	5 (29.4)	8	36.6	4 (22.2)	8	44.1	9 (39.1)	16	56.3
Severe RI (15-<30)				1 (100)	1	70.4	0		
Joint disorders									
Normal (>=90)	30 (11.3)	37	10.5	24 (8.9)	28	7.7	20 (7.7)	22	6.4
Mild RI (60-<90)	7 (5.8)	8	5.1	18 (15.8)	27	18.1	16 (13.3)	21	13.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	5 (21.7)	6	21.1
Severe RI (15-<30)				1 (100)	1	70.4	0		
Arthralgia									
Normal (>=90)	19 (7.2)	22	6.3	14 (5.2)	15	4.1	11 (4.2)	11	3.2
Mild RI (60-<90)	4 (3.3)	4	2.5	7 (6.1)	12	8.0	7 (5.8)	7	4.5
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	2 (8.7)	2	7.0
Severe RI (15-<30)				1 (100)	1	70.4	0		
Osteoarthritis									
Normal (>=90)	2 (0.8)	2	0.6	6 (2.2)	7	1.9	6 (2.3)	6	1.7
Mild RI (60-<90)	0			5 (4.4)	7	4.7	6 (5.0)	7	4.5
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Periarthritis									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			2 (1.8)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rotator cuff syndrome									
Normal (>=90)	4 (1.5)	5	1.4	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	2	1.3	2 (1.8)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Arthritis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spinal osteoarthritis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Joint swelling									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Arthritis climacteric									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Arthropathy									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Femoroacetabular impingement									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Gouty arthritis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Joint effusion									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neuropathic arthropathy									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				1	(4.3)	1	3.5
Severe RI (15-<30)					0				0			
Psoriatic arthropathy												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Rheumatoid arthritis												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				1	(0.8)	2	1.3
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Sacroiliitis												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Musculoskeletal and connective tissue disorders NEC												
Normal (>=90)	41	(15.5)	48	13.7	35	(13.0)	40	11.0	18	(6.9)	23	6.6
Mild RI (60-<90)	12	(10.0)	13	8.3	19	(16.7)	21	14.1	9	(7.5)	9	5.8
Moderate RI (30-<60)	4	(23.5)	5	22.9	2	(11.1)	5	27.6	6	(26.1)	6	21.1
Severe RI (15-<30)					0				0			
Back pain												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	23 (8.7)	25	7.1	16 (5.9)	17	4.7	10 (3.9)	11	3.2
Mild RI (60-<90)	5 (4.2)	5	3.2	9 (7.9)	10	6.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			2 (11.1)	3	16.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Pain in extremity									
Normal (>=90)	9 (3.4)	9	2.6	10 (3.7)	10	2.7	5 (1.9)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	4 (3.5)	4	2.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	2 (11.8)	2	9.2	2 (11.1)	2	11.0	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Neck pain									
Normal (>=90)	1 (0.4)	1	0.3	6 (2.2)	6	1.6	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Musculoskeletal pain									
Normal (>=90)	4 (1.5)	4	1.1	6 (2.2)	6	1.6	2 (0.8)	2	0.6
Mild RI (60-<90)	4 (3.3)	4	2.5	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Flank pain									
Normal (>=90)	3 (1.1)	3	0.9	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Muscle contracture									
Normal (>=90)	0			0			0		

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RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neck mass									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rheumatic disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Musculoskeletal chest pain									
Normal (>=90)	4 (1.5)	5	1.4	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Axillary mass									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Limb mass									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.9)	2	9.2	0			0		
Severe RI (15-<30)				0			0		
Musculoskeletal discomfort									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Musculoskeletal stiffness									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Plantar fasciitis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Muscle disorders									
Normal (>=90)	8 (3.0)	12	3.4	5 (1.9)	7	1.9	3 (1.2)	3	0.9
Mild RI (60-<90)	4 (3.3)	4	2.5	4 (3.5)	4	2.7	3 (2.5)	4	2.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Muscle spasms									
Normal (>=90)	4 (1.5)	5	1.4	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	3 (2.5)	3	1.9	3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Myalgia									
Normal (>=90)	5 (1.9)	7	2.0	4 (1.5)	6	1.6	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	3	1.9
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Diastasis recti abdominis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Muscular weakness									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendon, ligament and cartilage disorders									
Normal (>=90)	5 (1.9)	5	1.4	1 (0.4)	1	0.3	4 (1.5)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	3	2.0	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Trigger finger									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Osteochondrosis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendon disorder									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendonitis									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Costochondritis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ligament calcification									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Meniscal degeneration									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendon pain									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Synovial and bursal disorders									
Normal (>=90)	0			2 (0.7)	2	0.5	3 (1.2)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Bursitis									
Normal (>=90)	0			2 (0.7)	2	0.5	3 (1.2)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Bone disorders (excl congenital and fractures)									
Normal (>=90)	4 (1.5)	4	1.1	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	3	2.0	3 (2.5)	3	1.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bone lesion									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Osteopenia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Osteoporosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Exostosis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Bone pain									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metatarsalgia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Osteitis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	1	0.3	4 (1.5)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	2	1.3	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Intervertebral disc protrusion									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Foot deformity									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Intervertebral disc degeneration									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Scoliosis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spinal flattening									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spondylolisthesis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Connective tissue disorders (excl congenital)									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Polymyalgia rheumatica									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Investigations									
Normal (>=90)	15 (5.7)	17	4.8	24 (8.9)	29	8.0	23 (8.9)	31	9.0
Mild RI (60-<90)	3 (2.5)	6	3.8	12 (10.5)	15	10.0	9 (7.5)	9	5.8
Moderate RI (30-<60)	0			3 (16.7)	3	16.5	1 (4.3)	2	7.0
Severe RI (15-<30)				1 (100)	1	70.4	0		
Renal and urinary tract investigations and urinalyses									
Normal (>=90)	0			3 (1.1)	3	0.8	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				1 (100)	1	70.4	0		
Urine albumin/creatinine ratio increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				1 (100)	1	70.4	0		
Glomerular filtration rate decreased									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Urine albumin/creatinine ratio abnormal									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac and vascular investigations (excl enzyme tests)									
Normal (>=90)	2	(0.8)	2 0.6	3	(1.1)	3 0.8	2	(0.8)	2 0.6
Mild RI (60-<90)	0			4	(3.5)	5 3.3	2	(1.7)	2 1.3
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Blood pressure decreased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Blood pressure increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac murmur									
Normal (>=90)	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac stress test abnormal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Carotid pulse decreased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Electrocardiogram Q waves									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Heart rate increased									
Normal (>=90)	2	(0.8)	2 0.6	2	(0.7)	2 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Electrocardiogram QT prolonged									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Electrocardiogram PR prolongation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Electrocardiogram ST-T segment abnormal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal investigations									
Normal (>=90)	3 (1.1)	3	0.9	2 (0.7)	2	0.5	2 (0.8)	2	0.6
Mild RI (60-<90)	2 (1.7)	2	1.3	3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	2	7.0
Severe RI (15-<30)				0			0		
Colonoscopy normal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Lipase increased									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	2	1.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Occult blood positive									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Occult blood									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Amylase increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Faecal volume increased									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pancreatic enzymes increased									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Enzyme investigations NEC									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood creatine phosphokinase increased									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatobiliary investigations									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	6 (2.3)	9	2.6
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatic enzyme increased									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Liver function test abnormal									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Liver function test increased												
Normal (>=90)	0				1	(0.4)	1	0.3	1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Alanine aminotransferase increased												
Normal (>=90)	0				0				3	(1.2)	3	0.9
Mild RI (60-<90)	1	(0.8)	1	0.6	0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Aspartate aminotransferase increased												
Normal (>=90)	0				0				2	(0.8)	2	0.6
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Blood bilirubin increased												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Transaminases increased												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Endocrine investigations (incl sex hormones)									
Normal (>=90)	2 (0.8)	2	0.6	4 (1.5)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood thyroid stimulating hormone decreased									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood thyroid stimulating hormone increased									
Normal (>=90)	1 (0.4)	1	0.3	2 (0.7)	2	0.5	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood parathyroid hormone increased									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haematology investigations (incl blood groups)									
Normal (>=90)	0			4 (1.5)	6	1.6	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haemoglobin decreased									
Normal (>=90)	0			3 (1.1)	3	0.8	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haematocrit decreased									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Platelet count decreased									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Physical examination and organ system status topics									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Weight decreased									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Weight increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Protein and chemistry analyses NEC									
Normal (>=90)	2 (0.8)	2	0.6	0			4 (1.5)	4	1.2
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
C-reactive protein increased									
Normal (>=90)	2 (0.8)	2	0.6	0			4 (1.5)	4	1.2
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive organ and breast investigations (excl hormone analyses)									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mammogram abnormal									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lipid analyses									
Normal (>=90)	0			2	(0.7)	2 0.5	1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lipids abnormal									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Low density lipoprotein increased									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood cholesterol increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood triglycerides increased									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Investigations, imaging and histopathology procedures NEC									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Endoscopy abnormal									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metabolic, nutritional and blood gas investigations									
Normal (>=90)	2	(0.8)	2 0.6	1	(0.4)	1 0.3	6	(2.3)	7 2.0
Mild RI (60-<90)	1	(0.8)	1 0.6	0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vitamin B12 decreased									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood glucose decreased									
Normal (>=90)	1	(0.4)	1 0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood glucose increased									
Normal (>=90)	0			0			3	(1.2)	3 0.9
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood uric acid increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Brain natriuretic peptide increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Glycosylated haemoglobin increased									
Normal (>=90)	1	(0.4)	1 0.3	0			3	(1.2)	3 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Microbiology and serology investigations									
Normal (>=90)	0			1	(0.4)	1 0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Helicobacter test positive									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neurological, special senses and psychiatric investigations									
Normal (>=90)	0			1	(0.4)	2 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Intraocular pressure increased									
Normal (>=90)	0			1	(0.4)	2 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Water, electrolyte and mineral investigations									
Normal (>=90)	2	(0.8)	2 0.6	1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood potassium increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood potassium decreased									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood sodium increased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cytogenetic investigations									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Prostatic specific antigen increased									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Immunology and allergy investigations									
Normal (>=90)	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Antinuclear antibody increased									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Infections and infestations									
Normal (>=90)	105 (39.6)	202	57.6	122 (45.2)	239	65.6	110 (42.5)	219	63.3
Mild RI (60-<90)	54 (45.0)	104	66.2	50 (43.9)	98	65.6	54 (45.0)	110	71.5
Moderate RI (30-<60)	7 (41.2)	12	55.0	7 (38.9)	8	44.1	11 (47.8)	30	105.6
Severe RI (15-<30)				0			0		
Infections - pathogen unspecified									
Normal (>=90)	94 (35.5)	163	46.5	107 (39.6)	197	54.1	89 (34.4)	165	47.7
Mild RI (60-<90)	47 (39.2)	82	52.2	48 (42.1)	84	56.3	48 (40.0)	95	61.7
Moderate RI (30-<60)	5 (29.4)	5	22.9	7 (38.9)	8	44.1	10 (43.5)	21	73.9
Severe RI (15-<30)				0			0		
Nasopharyngitis									
Normal (>=90)	30 (11.3)	41	11.7	48 (17.8)	87	23.9	37 (14.3)	58	16.8
Mild RI (60-<90)	17 (14.2)	28	17.8	17 (14.9)	25	16.7	18 (15.0)	27	17.5
Moderate RI (30-<60)	0			3 (16.7)	3	16.5	4 (17.4)	7	24.6
Severe RI (15-<30)				0			0		
Upper respiratory tract infection									
Normal (>=90)	23 (8.7)	38	10.8	26 (9.6)	30	8.2	18 (6.9)	24	6.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	12 (10.0)	14	8.9	14 (12.3)	16	10.7	17 (14.2)	22	14.3
Moderate RI (30-<60)	2 (11.8)	2	9.2	2 (11.1)	2	11.0	3 (13.0)	4	14.1
Severe RI (15-<30)				0			0		
Bronchitis									
Normal (>=90)	6 (2.3)	7	2.0	7 (2.6)	8	2.2	8 (3.1)	10	2.9
Mild RI (60-<90)	4 (3.3)	4	2.5	6 (5.3)	7	4.7	4 (3.3)	4	2.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Sinusitis									
Normal (>=90)	5 (1.9)	5	1.4	8 (3.0)	13	3.6	5 (1.9)	6	1.7
Mild RI (60-<90)	0			5 (4.4)	5	3.3	6 (5.0)	7	4.5
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Urinary tract infection									
Normal (>=90)	11 (4.2)	13	3.7	9 (3.3)	12	3.3	6 (2.3)	8	2.3
Mild RI (60-<90)	6 (5.0)	8	5.1	3 (2.6)	3	2.0	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	2 (8.7)	3	10.6
Severe RI (15-<30)				0			0		
Gastroenteritis									
Normal (>=90)	19 (7.2)	22	6.3	11 (4.1)	12	3.3	9 (3.5)	10	2.9
Mild RI (60-<90)	5 (4.2)	6	3.8	3 (2.6)	3	2.0	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Conjunctivitis									
Normal (>=90)	2 (0.8)	4	1.1	2 (0.7)	2	0.5	2 (0.8)	3	0.9
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	3	2.0	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cystitis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	3 (1.2)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tonsillitis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	4 (1.5)	4	1.2
Mild RI (60-<90)	0			3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Paronychia									
Normal (>=90)	1 (0.4)	1	0.3	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Localised infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tooth infection									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	2	1.3	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Gastrointestinal infection									
Normal (>=90)	1 (0.4)	1	0.3	2 (0.7)	3	0.8	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pharyngitis									
Normal (>=90)	1 (0.4)	1	0.3	2 (0.7)	2	0.5	4 (1.5)	4	1.2
Mild RI (60-<90)	0			1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Pneumonia									
Normal (>=90)	1 (0.4)	1	0.3	4 (1.5)	5	1.4	3 (1.2)	3	0.9
Mild RI (60-<90)	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Acute sinusitis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	3 (2.5)	3	1.9	1 (0.9)	1	0.7	2 (1.7)	4	2.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Otitis externa									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lower respiratory tract infection									
Normal (>=90)	1 (0.4)	1	0.3	3 (1.1)	3	0.8	3 (1.2)	3	0.9
Mild RI (60-<90)	2 (1.7)	2	1.3	0			3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abscess									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chronic sinusitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mastitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Otitis media acute									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Respiratory tract infection									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	4 (3.3)	4	2.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tooth abscess									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	3 (2.5)	3	1.9	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			1 (4.3)	2	7.0
Severe RI (15-<30)				0			0		
Urosepsis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Appendicitis									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Breast abscess									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diverticulitis									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Implant site infection									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Infected dermal cyst									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Kidney infection									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Periodontitis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post procedural infection									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rhinitis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin infection									
Normal (>=90)	0			1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulvovaginitis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Colonic abscess									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ear infection									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Empyema									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eye infection									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gingival abscess									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gingivitis									
Normal (>=90)	0			0			3	(1.2)	3 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hordeolum									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Joint abscess									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Labyrinthitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Laryngitis									
Normal (>=90)	2 (0.8)	3	0.9	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mastoiditis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Osteomyelitis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Otitis media									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Otitis media chronic									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pericoronitis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Postoperative wound infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pulpitis dental									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pyelonephritis acute									
Normal (>=90)	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sepsis									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sialoadenitis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sinobronchitis									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Subcutaneous abscess									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tracheitis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tracheobronchitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vaginal infection									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Wound infection									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Viral infectious disorders									
Normal (>=90)	20 (7.5)	24	6.8	29 (10.7)	33	9.1	20 (7.7)	25	7.2
Mild RI (60-<90)	12 (10.0)	14	8.9	7 (6.1)	8	5.4	12 (10.0)	12	7.8
Moderate RI (30-<60)	3 (17.6)	3	13.7	0			4 (17.4)	5	17.6
Severe RI (15-<30)				0			0		
Influenza									
Normal (>=90)	7 (2.6)	8	2.3	13 (4.8)	14	3.8	14 (5.4)	17	4.9
Mild RI (60-<90)	9 (7.5)	10	6.4	2 (1.8)	2	1.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			2 (8.7)	3	10.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Gastroenteritis viral									
Normal (>=90)	4 (1.5)	4	1.1	5 (1.9)	6	1.6	3 (1.2)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	4 (3.3)	4	2.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Viral infection									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	3	0.8	1 (0.4)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Herpes zoster									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Herpes virus infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Oral herpes									
Normal (>=90)	2 (0.8)	3	0.9	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastroenteritis norovirus									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Herpes simplex									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ophthalmic herpes zoster									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pneumonia influenzal									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Respiratory tract infection viral									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Viral diarrhoea									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Viral pharyngitis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chikungunya virus infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ear infection viral									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Rhinovirus infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Viral upper respiratory tract infection									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	3 (1.1)	4	1.1	0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bacterial infectious disorders									
Normal (>=90)	4 (1.5)	4	1.1	4 (1.5)	4	1.1	9 (3.5)	13	3.8
Mild RI (60-<90)	4 (3.3)	5	3.2	4 (3.5)	4	2.7	1 (0.8)	2	1.3
Moderate RI (30-<60)	2 (11.8)	4	18.3	0			2 (8.7)	3	10.6
Severe RI (15-<30)				0			0		
Cellulitis									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	2 (1.7)	3	1.9	1 (0.9)	1	0.7	1 (0.8)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Furuncle									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pharyngitis streptococcal									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Staphylococcal infection									
Normal (>=90)	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			1	(4.3)	2 7.0
Severe RI (15-<30)				0			0		
Bacterial vaginosis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Breast cellulitis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ear infection bacterial									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1	(5.9)	3 13.7	0			0		
Severe RI (15-<30)				0			0		
Clostridium difficile colitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Helicobacter gastritis									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Helicobacter infection									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Wound infection staphylococcal									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Fungal infectious disorders									
Normal (>=90)	11 (4.2)	11	3.1	5 (1.9)	5	1.4	13 (5.0)	15	4.3
Mild RI (60-<90)	3 (2.5)	3	1.9	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Onychomycosis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulvovaginal candidiasis									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Fungal infection									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Fungal skin infection									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tinea pedis									
Normal (>=90)	0			1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulvovaginal mycotic infection									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Balanitis candida									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Candida infection									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatophytosis of nail									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Genital candidiasis									
Normal (>=90)	2 (0.8)	2	0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Genital infection fungal									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin candida									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tinea infection									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tinea versicolour									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	2 (1.7)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ectoparasitic disorders									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Acarodermatitis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nervous system disorders									
Normal (>=90)	38 (14.3)	67	19.1	41 (15.2)	53	14.6	33 (12.7)	50	14.5
Mild RI (60-<90)	21 (17.5)	32	20.4	35 (30.7)	54	36.2	23 (19.2)	33	21.4
Moderate RI (30-<60)	4 (23.5)	6	27.5	6 (33.3)	11	60.6	7 (30.4)	9	31.7
Severe RI (15-<30)				0			0		
Headaches									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	25 (9.4)	42	12.0	19 (7.0)	26	7.1	14 (5.4)	21	6.1
Mild RI (60-<90)	9 (7.5)	12	7.6	14 (12.3)	15	10.0	7 (5.8)	8	5.2
Moderate RI (30-<60)	2 (11.8)	2	9.2	4 (22.2)	5	27.6	3 (13.0)	3	10.6
Severe RI (15-<30)				0			0		
Headache									
Normal (>=90)	24 (9.1)	38	10.8	16 (5.9)	23	6.3	13 (5.0)	19	5.5
Mild RI (60-<90)	8 (6.7)	9	5.7	12 (10.5)	13	8.7	5 (4.2)	6	3.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	3 (16.7)	4	22.0	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Migraine									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Tension headache									
Normal (>=90)	3 (1.1)	3	0.9	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Migraine with aura									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Occipital neuralgia									
Normal (>=90)	0			0			1 (0.4)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sinus headache									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Neurological disorders NEC									
Normal (>=90)	13 (4.9)	16	4.6	12 (4.4)	14	3.8	14 (5.4)	16	4.6
Mild RI (60-<90)	11 (9.2)	13	8.3	22 (19.3)	30	20.1	14 (11.7)	19	12.3
Moderate RI (30-<60)	4 (23.5)	4	18.3	2 (11.1)	2	11.0	3 (13.0)	3	10.6
Severe RI (15-<30)				0			0		
Dizziness									
Normal (>=90)	8 (3.0)	10	2.9	6 (2.2)	6	1.6	8 (3.1)	10	2.9
Mild RI (60-<90)	7 (5.8)	8	5.1	12 (10.5)	13	8.7	5 (4.2)	5	3.2
Moderate RI (30-<60)	3 (17.6)	3	13.7	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Dysgeusia									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			2 (1.8)	6	4.0	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Paraesthesia									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	3 (1.2)	3	0.9
Mild RI (60-<90)	0			3 (2.6)	5	3.3	2 (1.7)	3	1.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Hyperaesthesia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Somnolence									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypoaesthesia									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dizziness postural									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Syncope									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	2 (1.7)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Ageusia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aphasia									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Coordination abnormal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dysaesthesia									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Head discomfort									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hypogeusia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lethargy									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Loss of consciousness									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Neuralgia									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Phantom limb syndrome									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Presyncope									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Restless legs syndrome												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Central nervous system vascular disorders												
Normal (>=90)	1	(0.4)	1	0.3	3	(1.1)	3	0.8	1	(0.4)	2	0.6
Mild RI (60-<90)	1	(0.8)	1	0.6	3	(2.6)	4	2.7	1	(0.8)	1	0.6
Moderate RI (30-<60)	0				2	(11.1)	4	22.0	0			
Severe RI (15-<30)					0				0			
Cerebrovascular accident												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Cerebral artery thrombosis												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Spinal epidural haematoma												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Subarachnoid haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Carotid artery stenosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	2	(1.8)	2 1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Carotid arteriosclerosis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cerebral artery stenosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cerebral infarction									
Normal (>=90)	0			1	(0.4)	1 0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ischaemic stroke									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral neuropathies									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	5 (1.9)	6	1.7
Mild RI (60-<90)	4 (3.3)	5	3.2	2 (1.8)	2	1.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Carpal tunnel syndrome									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	3 (2.5)	4	2.5	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diabetic neuropathy									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Meralgia paraesthetica									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neuropathy peripheral									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	2	0.6
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nerve compression									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Polyneuropathy									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spinal cord and nerve root disorders									
Normal (>=90)	5 (1.9)	5	1.4	3 (1.1)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sciatica									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Radiculopathy									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sacral radiculopathy									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cervical radiculopathy									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cervicobrachial syndrome									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lumbar radiculopathy									
Normal (>=90)	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mental impairment disorders									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Memory impairment									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Amnesia									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Dementia Alzheimer's type									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vascular dementia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sleep disturbances (incl subtypes)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0			0				0			
Mild RI (60-<90)	0			1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0			0				0			
Severe RI (15-<30)				0				0			
Hypersomnia											
Normal (>=90)	0			0				0			
Mild RI (60-<90)	0			1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0			0				0			
Severe RI (15-<30)				0				0			
Structural brain disorders											
Normal (>=90)	0			0				0			
Mild RI (60-<90)	0			1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0			0				0			
Severe RI (15-<30)				0				0			
Cerebral ventricle dilatation											
Normal (>=90)	0			0				0			
Mild RI (60-<90)	0			1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0			0				0			
Severe RI (15-<30)				0				0			
Cranial nerve disorders (excl neoplasms)											
Normal (>=90)	0			2	(0.7)	2	0.5	0			
Mild RI (60-<90)	0			0				0			
Moderate RI (30-<60)	0			0				0			
Severe RI (15-<30)				0				0			
Anosmia											

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Facial paralysis												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Encephalopathies												
Normal (>=90)	0				2	(0.7)	2	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Hepatic encephalopathy												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Hyponatraemic encephalopathy												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Movement disorders (incl parkinsonism)												
Normal (>=90)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tremor									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neurological disorders of the eye									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Visual field defect									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Seizures (incl subtypes)									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Partial seizures									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
General disorders and administration site conditions									
Normal (>=90)	29 (10.9)	38	10.8	43 (15.9)	55	15.1	26 (10.0)	35	10.1
Mild RI (60-<90)	22 (18.3)	31	19.7	22 (19.3)	32	21.4	15 (12.5)	18	11.7
Moderate RI (30-<60)	0			4 (22.2)	6	33.1	5 (21.7)	8	28.2
Severe RI (15-<30)				0			0		
General system disorders NEC									
Normal (>=90)	23 (8.7)	28	8.0	33 (12.2)	38	10.4	15 (5.8)	17	4.9
Mild RI (60-<90)	17 (14.2)	24	15.3	20 (17.5)	25	16.7	10 (8.3)	10	6.5
Moderate RI (30-<60)	0			4 (22.2)	5	27.6	3 (13.0)	3	10.6
Severe RI (15-<30)				0			0		
Fatigue									
Normal (>=90)	10 (3.8)	12	3.4	15 (5.6)	16	4.4	3 (1.2)	3	0.9
Mild RI (60-<90)	9 (7.5)	14	8.9	10 (8.8)	10	6.7	0		
Moderate RI (30-<60)	0			3 (16.7)	3	16.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Malaise									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	2	1.3	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Oedema peripheral									
Normal (>=90)	0			0			2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Asthenia									
Normal (>=90)	3 (1.1)	3	0.9	5 (1.9)	5	1.4	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Influenza like illness									
Normal (>=90)	0			3 (1.1)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Early satiety									
Normal (>=90)	4 (1.5)	4	1.1	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral swelling									
Normal (>=90)	0			1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Non-cardiac chest pain									
Normal (>=90)	0			3 (1.1)	3	0.8	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pain									
Normal (>=90)	4 (1.5)	4	1.1	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chest discomfort									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chest pain									
Normal (>=90)	0			0			1 (0.4)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Face oedema									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hunger									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Thirst decreased									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Feeling cold									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Swelling									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chills									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Discomfort									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Inflammation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Polyp									
Normal (>=90)	1	(0.4)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sensation of foreign body									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Thirst									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Administration site reactions									
Normal (>=90)	4	(1.5)	5 1.4	8	(3.0)	12 3.3	4	(1.5)	7 2.0
Mild RI (60-<90)	2	(1.7)	2 1.3	4	(3.5)	6 4.0	4	(3.3)	6 3.9
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	2	(8.7)	5 17.6
Severe RI (15-<30)				0			0		
Injection site bruising									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.2)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Injection site pain									
Normal (>=90)	4 (1.5)	4	1.1	4 (1.5)	5	1.4	1 (0.4)	1	0.3
Mild RI (60-<90)	0			3 (2.6)	4	2.7	1 (0.8)	3	1.9
Moderate RI (30-<60)	0			0			1 (4.3)	3	10.6
Severe RI (15-<30)				0			0		
Injection site erythema									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injection site reaction									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Implant site pain									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injection site mass									
Normal (>=90)	0			1 (0.4)	2	0.5	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injection site discomfort									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injection site haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injection site urticaria									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Body temperature conditions									
Normal (>=90)	4 (1.5)	4	1.1	4 (1.5)	4	1.1	8 (3.1)	11	3.2
Mild RI (60-<90)	5 (4.2)	5	3.2	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pyrexia									
Normal (>=90)	4 (1.5)	4	1.1	4 (1.5)	4	1.1	8 (3.1)	11	3.2
Mild RI (60-<90)	5 (4.2)	5	3.2	0			1 (0.8)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tissue disorders NEC									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mass									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nodule									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Therapeutic and nontherapeutic effects (excl toxicity)									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Drug intolerance									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Complications associated with device									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Complication associated with device									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Respiratory, thoracic and mediastinal disorders									
Normal (>=90)	24 (9.1)	30	8.6	25 (9.3)	30	8.2	27 (10.4)	30	8.7
Mild RI (60-<90)	9 (7.5)	10	6.4	17 (14.9)	24	16.1	7 (5.8)	11	7.1
Moderate RI (30-<60)	3 (17.6)	4	18.3	5 (27.8)	8	44.1	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Respiratory tract signs and symptoms									
Normal (>=90)	9 (3.4)	9	2.6	10 (3.7)	10	2.7	7 (2.7)	7	2.0
Mild RI (60-<90)	2 (1.7)	2	1.3	7 (6.1)	7	4.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	2 (11.8)	2	9.2	2 (11.1)	2	11.0	0		
Severe RI (15-<30)				0			0		
Dysphonia									
Normal (>=90)	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hiccups									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Oropharyngeal pain									
Normal (>=90)	5 (1.9)	5	1.4	4 (1.5)	4	1.1	4 (1.5)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	3 (2.6)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Rhinorrhoea									
Normal (>=90)	3 (1.1)	3	0.9	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Oropharyngeal discomfort									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Upper respiratory tract congestion									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aphonia									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dry throat									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Painful respiration									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nasal discomfort									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Upper-airway cough syndrome									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Respiratory disorders NEC									
Normal (>=90)	8 (3.0)	9	2.6	9 (3.3)	9	2.5	11 (4.2)	11	3.2
Mild RI (60-<90)	6 (5.0)	6	3.8	7 (6.1)	7	4.7	3 (2.5)	6	3.9
Moderate RI (30-<60)	2 (11.8)	2	9.2	2 (11.1)	3	16.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Respiratory disorder									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	2 (1.7)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Pulmonary mass									
Normal (>=90)	1 (0.4)	1	0.3	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Acute respiratory failure									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Cough									
Normal (>=90)	7 (2.6)	8	2.3	6 (2.2)	6	1.6	5 (1.9)	5	1.4
Mild RI (60-<90)	2 (1.7)	2	1.3	3 (2.6)	3	2.0	2 (1.7)	3	1.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Productive cough									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sleep apnoea syndrome									
Normal (>=90)	0			0			3 (1.2)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Dyspnoea									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypoxia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bronchial disorders (excl neoplasms)									
Normal (>=90)	4 (1.5)	4	1.1	3 (1.1)	4	1.1	4 (1.5)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	4	2.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Asthma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	3 (1.1)	3	0.9	2 (0.7)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Bronchospasm									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chronic obstructive pulmonary disease									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Childhood asthma									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lower respiratory tract disorders (excl obstruction and infection)									
Normal (>=90)	1 (0.4)	2	0.6	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Atelectasis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Idiopathic interstitial pneumonia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Emphysema									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Upper respiratory tract disorders (excl infections)									
Normal (>=90)	5 (1.9)	6	1.7	6 (2.2)	7	1.9	7 (2.7)	8	2.3
Mild RI (60-<90)	1 (0.8)	1	0.6	4 (3.5)	5	3.3	0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Epistaxis									
Normal (>=90)	0			2 (0.7)	3	0.8	5 (1.9)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nasal congestion									
Normal (>=90)	2 (0.8)	3	0.9	0			1 (0.4)	2	0.6
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Rhinitis allergic									
Normal (>=90)	1 (0.4)	1	0.3	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sinus congestion									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pleural disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Pneumothorax									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolism and nutrition disorders									
Normal (>=90)	32 (12.1)	43	12.3	35 (13.0)	40	11.0	38 (14.7)	43	12.4
Mild RI (60-<90)	14 (11.7)	21	13.4	18 (15.8)	22	14.7	14 (11.7)	17	11.0
Moderate RI (30-<60)	2 (11.8)	4	18.3	3 (16.7)	4	22.0	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Appetite and general nutritional disorders									
Normal (>=90)	21 (7.9)	28	8.0	28 (10.4)	32	8.8	10 (3.9)	10	2.9
Mild RI (60-<90)	10 (8.3)	10	6.4	12 (10.5)	13	8.7	5 (4.2)	7	4.5
Moderate RI (30-<60)	1 (5.9)	2	9.2	1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Decreased appetite									
Normal (>=90)	19 (7.2)	23	6.6	25 (9.3)	27	7.4	9 (3.5)	9	2.6
Mild RI (60-<90)	9 (7.5)	9	5.7	12 (10.5)	13	8.7	5 (4.2)	7	4.5
Moderate RI (30-<60)	1 (5.9)	2	9.2	1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Hyperphagia									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Increased appetite									
Normal (>=90)	3 (1.1)	4	1.1	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Overweight									
Normal (>=90)	0			1 (0.4)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cachexia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Obesity									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Electrolyte and fluid balance conditions									
Normal (>=90)	4 (1.5)	5	1.4	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	3 (2.6)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			2 (11.1)	2	11.0	0		
Severe RI (15-<30)				0			0		
Dehydration									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hypokalaemia									
Normal (>=90)	2 (0.8)	3	0.9	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hyponatraemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperkalaemia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diabetic complications									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Diabetic ketoacidosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Diabetic metabolic decompensation									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lipid metabolism disorders									
Normal (>=90)	4 (1.5)	4	1.1	3 (1.1)	3	0.8	8 (3.1)	8	2.3
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dyslipidaemia									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	3	0.8	6 (2.3)	6	1.7
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperlipidaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertriglyceridaemia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypercholesterolaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Purine and pyrimidine metabolism disorders									
Normal (>=90)	1 (0.4)	1	0.3	0			3 (1.2)	5	1.4
Mild RI (60-<90)	2 (1.7)	3	1.9	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gout									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	4	1.2
Mild RI (60-<90)	2 (1.7)	3	1.9	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperuricaemia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vitamin related disorders									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vitamin B complex deficiency									
Normal (>=90)	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Folate deficiency									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vitamin D deficiency									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone, calcium, magnesium and phosphorus metabolism disorders									
Normal (>=90)	1 (0.4)	1	0.3	0			3 (1.2)	3	0.9
Mild RI (60-<90)	2 (1.7)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Hypomagnesaemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypercalcaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1	(5.9)	1 4.6	0			0		
Severe RI (15-<30)				0			0		
Hypercalcitoninaemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypocalcaemia									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Acid-base disorders									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ketoacidosis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lactic acidosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Glucose metabolism disorders (incl diabetes mellitus)									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	14 (5.4)	14	4.0
Mild RI (60-<90)	1 (0.8)	2	1.3	0			6 (5.0)	6	3.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Diabetes mellitus									
Normal (>=90)	0			1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diabetes mellitus inadequate control									
Normal (>=90)	0			0			5 (1.9)	5	1.4
Mild RI (60-<90)	1 (0.8)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperglycaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperinsulinaemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Hypoglycaemia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Type 2 diabetes mellitus									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Iron and trace metal metabolism disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Iron deficiency									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metabolism disorders NEC									
Normal (>=90)	1 (0.4)	2	0.6	0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperamylasaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperlipasaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Renal and urinary disorders									
Normal (>=90)	10 (3.8)	13	3.7	11 (4.1)	12	3.3	11 (4.2)	16	4.6
Mild RI (60-<90)	7 (5.8)	7	4.5	16 (14.0)	21	14.1	15 (12.5)	16	10.4
Moderate RI (30-<60)	2 (11.8)	2	9.2	4 (22.2)	4	22.0	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Urinary tract signs and symptoms									
Normal (>=90)	3 (1.1)	3	0.9	6 (2.2)	6	1.6	7 (2.7)	10	2.9
Mild RI (60-<90)	3 (2.5)	3	1.9	9 (7.9)	9	6.0	9 (7.5)	9	5.8
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	2	11.0	0		
Severe RI (15-<30)				0			0		
Haematuria									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			2	(11.1)	2 11.0	0		
Severe RI (15-<30)				0			0		
Dysuria									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			3	(2.6)	3 2.0	2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Microalbuminuria									
Normal (>=90)	0			3	(1.1)	3 0.8	0		
Mild RI (60-<90)	2	(1.7)	2 1.3	1	(0.9)	1 0.7	1	(0.8)	1 0.6
Moderate RI (30-<60)	1	(5.9)	1 4.6	0			0		
Severe RI (15-<30)				0			0		
Renal colic									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			2	(1.8)	2 1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nocturia									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Proteinuria									
Normal (>=90)	1	(0.4)	1 0.3	1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	0			1	(0.9)	1 0.7	1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Pollakiuria									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lower urinary tract symptoms									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Micturition disorder									
Normal (>=90)	0			0			1 (0.4)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Polyuria									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Urethral pain									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urinary incontinence									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Renal disorders (excl nephropathies)									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	4 (3.5)	6	4.0	4 (3.3)	4	2.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Acute kidney injury									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Renal cyst									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Chronic kidney disease									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Renal impairment									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hydronephrosis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Kidney fibrosis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Urolithiases									
Normal (>=90)	3 (1.1)	4	1.1	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	3 (2.5)	3	1.9	0			3 (2.5)	3	1.9
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Stag horn calculus									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Nephrolithiasis									
Normal (>=90)	3 (1.1)	4	1.1	2 (0.7)	2	0.5	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	3 (2.5)	3	1.9	0			3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Calculus urinary									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ureterolithiasis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Nephropathies									
Normal (>=90)	3 (1.1)	3	0.9	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			4 (3.5)	4	2.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Diabetic nephropathy									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			3 (2.6)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nephropathy									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bladder and bladder neck disorders (excl calculi)									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			2	(1.8)	2 1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bladder outlet obstruction									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertonic bladder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bladder hypertrophy									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eye disorders									
Normal (>=90)	27	(10.2)	41 11.7	28	(10.4)	36 9.9	18	(6.9)	27 7.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	18 (15.0)	23	14.6	20 (17.5)	29	19.4	18 (15.0)	23	14.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	4	22.0	6 (26.1)	6	21.1
Severe RI (15-<30)				0			0		
Retina, choroid and vitreous haemorrhages and vascular disorders									
Normal (>=90)	8 (3.0)	8	2.3	13 (4.8)	14	3.8	6 (2.3)	7	2.0
Mild RI (60-<90)	4 (3.3)	5	3.2	7 (6.1)	8	5.4	5 (4.2)	5	3.2
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Diabetic retinopathy									
Normal (>=90)	7 (2.6)	7	2.0	9 (3.3)	10	2.7	6 (2.3)	7	2.0
Mild RI (60-<90)	4 (3.3)	5	3.2	5 (4.4)	5	3.3	5 (4.2)	5	3.2
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Retinal haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinopathy hypertensive									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Non-proliferative retinopathy									
Normal (>=90)	0			2 (0.7)	2	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinal artery occlusion									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinopathy									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ocular infections, irritations and inflammations									
Normal (>=90)	10 (3.8)	10	2.9	5 (1.9)	6	1.6	5 (1.9)	5	1.4
Mild RI (60-<90)	3 (2.5)	3	1.9	2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	2	11.0	0		
Severe RI (15-<30)				0			0		
Macular oedema									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	2	11.0	0		
Severe RI (15-<30)				0			0		
Blepharitis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	2	0.5	2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Meibomian gland dysfunction									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eyelid rash									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Keratitis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ocular hyperaemia									
Normal (>=90)	0			1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Conjunctivitis allergic									
Normal (>=90)	2 (0.8)	2	0.6	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Episcleritis									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eye pruritus									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Punctate keratitis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Swelling of eyelid									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Uveitis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Ocular structural change, deposit and degeneration NEC									
Normal (>=90)	5 (1.9)	5	1.4	2 (0.7)	2	0.5	1 (0.4)	2	0.6
Mild RI (60-<90)	5 (4.2)	7	4.5	3 (2.6)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Vitreous detachment									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	2	1.3	0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Detachment of retinal pigment epithelium									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Macular fibrosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinal depigmentation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Optic disc disorder									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinal degeneration									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Age-related macular degeneration									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Choroidal dystrophy									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Macular degeneration									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Optic atrophy									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinal drusen									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vitreous floaters									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Anterior eye structural change, deposit and degeneration									
Normal (>=90)	6 (2.3)	6	1.7	3 (1.1)	3	0.8	3 (1.2)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	6 (5.3)	8	5.4	6 (5.0)	8	5.2
Moderate RI (30-<60)	0			0			3 (13.0)	3	10.6
Severe RI (15-<30)				0			0		
Cataract									
Normal (>=90)	4 (1.5)	4	1.1	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	4 (3.5)	5	3.3	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			0			2 (8.7)	2	7.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Cataract cortical									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Narrow anterior chamber angle									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	2 1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cataract subcapsular									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatochalasis									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Cataract nuclear									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			1	(0.8)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pinguecula									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Posterior capsule opacification									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eye disorders NEC									
Normal (>=90)	5 (1.9)	5	1.4	3 (1.1)	3	0.8	4 (1.5)	4	1.2
Mild RI (60-<90)	3 (2.5)	3	1.9	5 (4.4)	5	3.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Dry eye									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	3 (1.2)	3	0.9
Mild RI (60-<90)	2 (1.7)	2	1.3	4 (3.5)	4	2.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vitreous disorder									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lacrimation increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eyelid disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Retinal disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vision disorders									
Normal (>=90)	5 (1.9)	5	1.4	4 (1.5)	4	1.1	4 (1.5)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	1 (0.9)	1	0.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vision blurred									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Myopia									
Normal (>=90)	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Visual impairment									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Astigmatism									
Normal (>=90)	0			0			3 (1.2)	3	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypermetropia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pathologic myopia									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Presbyopia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Glaucoma and ocular hypertension									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Glaucoma									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ocular haemorrhages and vascular disorders NEC									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Eye haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Conjunctival haemorrhage									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Optic disc haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ocular neuromuscular disorders									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eyelid ptosis									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ocular sensory symptoms NEC									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Asthenopia									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Injury, poisoning and procedural complications									
Normal (>=90)	36 (13.6)	46	13.1	31 (11.5)	42	11.5	34 (13.1)	40	11.6
Mild RI (60-<90)	14 (11.7)	24	15.3	15 (13.2)	17	11.4	13 (10.8)	17	11.0
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	9	49.6	2 (8.7)	4	14.1
Severe RI (15-<30)				0			0		
Injuries NEC									
Normal (>=90)	26 (9.8)	34	9.7	23 (8.5)	27	7.4	25 (9.7)	27	7.8
Mild RI (60-<90)	10 (8.3)	14	8.9	8 (7.0)	9	6.0	9 (7.5)	11	7.1
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	3	16.5	2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Skin laceration									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Road traffic accident									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Traumatic haemothorax									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Muscle strain									
Normal (>=90)	3 (1.1)	3	0.9	6 (2.2)	6	1.6	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Fall									
Normal (>=90)	4 (1.5)	4	1.1	5 (1.9)	6	1.6	1 (0.4)	2	0.6
Mild RI (60-<90)	4 (3.3)	4	2.5	0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Ligament sprain									
Normal (>=90)	5 (1.9)	7	2.0	2 (0.7)	2	0.5	5 (1.9)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone contusion									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Contusion									
Normal (>=90)	0			1 (0.4)	1	0.3	3 (1.2)	4	1.2
Mild RI (60-<90)	0			1 (0.9)	2	1.3	5 (4.2)	5	3.2
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Limb injury									
Normal (>=90)	3 (1.1)	3	0.9	3 (1.1)	3	0.8	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Animal bite									
Normal (>=90)	0			0			2 (0.8)	2	0.6
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Arthropod sting									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post-traumatic pain									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Epicondylitis									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Face injury									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Head injury									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Muscle injury									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin abrasion									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tooth fracture									
Normal (>=90)	3 (1.1)	3	0.9	1 (0.4)	1	0.3	3 (1.2)	3	0.9
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abdominal injury									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Arthropod bite												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Chest injury												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				1	(4.3)	1	3.5
Severe RI (15-<30)					0				0			
Craniocerebral injury												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Foreign body in eye												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Injury corneal												
Normal (>=90)	0				0				1	(0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ligament rupture									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Muscle rupture									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post-traumatic neck syndrome									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Soft tissue injury									
Normal (>=90)	4 (1.5)	4	1.1	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spinal column injury									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Subdural haematoma									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendon injury									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tendon rupture									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Wound									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone and joint injuries									
Normal (>=90)	5	(1.9)	6 1.7	8	(3.0)	9 2.5	9	(3.5)	9 2.6
Mild RI (60-<90)	3	(2.5)	3 1.9	5	(4.4)	5 3.3	3	(2.5)	3 1.9
Moderate RI (30-<60)	0			1	(5.6)	5 27.6	1	(4.3)	1 3.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Rib fracture												
Normal (>=90)	0				2	(0.7)	2	0.5	0			
Mild RI (60-<90)	0				1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Cervical vertebral fracture												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Spinal compression fracture												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Thoracic vertebral fracture												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			
Upper limb fracture												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Foot fracture									
Normal (>=90)	0			2 (0.7)	2	0.5	2 (0.8)	2	0.6
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Joint injury									
Normal (>=90)	1 (0.4)	1	0.3	0			3 (1.2)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Stress fracture									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Humerus fracture									
Normal (>=90)	0			2 (0.7)	2	0.5	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Meniscus injury									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Radius fracture									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Wrist fracture									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ankle fracture									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone fissure									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cartilage injury									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hand fracture									
Normal (>=90)	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hip fracture									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Joint dislocation									
Normal (>=90)	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lisfranc fracture									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spinal fracture									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sternal fracture									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Procedural related injuries and complications NEC									
Normal (>=90)	1 (0.4)	1	0.3	3 (1.1)	3	0.8	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Post procedural haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Anaemia postoperative									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Graft complication									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Procedural pain									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dental restoration failure									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Incision site pain									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post procedural complication									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Surgical skin tear									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Injuries by physical agents									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Sunburn									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypobarism									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Thermal burn									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Heat illness									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Medication errors and other product use errors and issues									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	2	0.6
Mild RI (60-<90)	3 (2.5)	6	3.8	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Extra dose administered									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Accidental overdose									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	2	0.6
Mild RI (60-<90)	2 (1.7)	4	2.5	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dose calculation error									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Incorrect dose administered									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Overdoses and underdoses NEC									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Intentional overdose									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac disorders									
Normal (>=90)	12 (4.5)	13	3.7	13 (4.8)	18	4.9	7 (2.7)	7	2.0
Mild RI (60-<90)	7 (5.8)	9	5.7	5 (4.4)	6	4.0	5 (4.2)	9	5.8
Moderate RI (30-<60)	1 (5.9)	2	9.2	4 (22.2)	4	22.0	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Cardiac arrhythmias									
Normal (>=90)	7 (2.6)	7	2.0	7 (2.6)	9	2.5	1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	3	1.9	3 (2.6)	4	2.7	2 (1.7)	3	1.9
Moderate RI (30-<60)	1 (5.9)	2	9.2	3 (16.7)	3	16.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Atrial fibrillation									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			3 (16.7)	3	16.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Supraventricular extrasystoles									
Normal (>=90)	0			3 (1.1)	3	0.8	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tachycardia									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ventricular extrasystoles									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Atrioventricular block first degree									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bundle branch block right									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sinus tachycardia									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Supraventricular tachycardia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Atrial flutter									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bradycardia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bundle branch block left									
Normal (>=90)	2 (0.8)	2	0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Coronary artery disorders									
Normal (>=90)	4 (1.5)	4	1.1	5 (1.9)	5	1.4	3 (1.2)	3	0.9
Mild RI (60-<90)	3 (2.5)	3	1.9	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Myocardial infarction									
Normal (>=90)	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Acute myocardial infarction									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Angina pectoris									
Normal (>=90)	0			2 (0.7)	2	0.5	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Angina unstable									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Coronary artery disease									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Myocardial ischaemia									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Arteriosclerosis coronary artery									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac disorders, signs and symptoms NEC									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	3	0.8	3 (1.2)	3	0.9
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Palpitations									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiovascular disorder									
Normal (>=90)	0			1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertensive heart disease									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Heart failures									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			2	(1.7)	3 1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac failure congestive									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac failure acute									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Left ventricular failure									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Myocardial disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Cardiac hypertrophy												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Left ventricular hypertrophy												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Skin and subcutaneous tissue disorders												
Normal (>=90)	24	(9.1)	27	7.7	22	(8.1)	31	8.5	20	(7.7)	22	6.4
Mild RI (60-<90)	12	(10.0)	13	8.3	17	(14.9)	22	14.7	13	(10.8)	15	9.7
Moderate RI (30-<60)	2	(11.8)	3	13.7	1	(5.6)	1	5.5	4	(17.4)	5	17.6
Severe RI (15-<30)					0				0			
Epidermal and dermal conditions												
Normal (>=90)	16	(6.0)	17	4.8	15	(5.6)	20	5.5	13	(5.0)	14	4.0
Mild RI (60-<90)	5	(4.2)	5	3.2	11	(9.6)	14	9.4	8	(6.7)	8	5.2
Moderate RI (30-<60)	2	(11.8)	3	13.7	1	(5.6)	1	5.5	1	(4.3)	1	3.5
Severe RI (15-<30)					0				0			
Sensitive skin												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				1	(5.6)	1	5.5	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Rash									
Normal (>=90)	4 (1.5)	4	1.1	6 (2.2)	9	2.5	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eczema									
Normal (>=90)	3 (1.1)	3	0.9	2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Dry skin									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blister									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			2 (1.8)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rash pruritic									
Normal (>=90)	1 (0.4)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Decubitus ulcer									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Intertrigo									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pain of skin									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pruritus									
Normal (>=90)	2	(0.8)	2 0.6	0			3	(1.2)	3 0.9
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin exfoliation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatitis allergic									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatitis contact									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Drug eruption									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.8)	3	0.9
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Perioral dermatitis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Psoriasis									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin burning sensation									
Normal (>=90)	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin lesion									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatitis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Erythema									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	2	9.2	0			0		
Severe RI (15-<30)				0			0		
Neurodermatitis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Parapsoriasis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Rash erythematous									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Stasis dermatitis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Xanthelasma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin appendage conditions									
Normal (>=90)	7 (2.6)	7	2.0	5 (1.9)	6	1.6	5 (1.9)	5	1.4
Mild RI (60-<90)	4 (3.3)	4	2.5	4 (3.5)	6	4.0	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Alopecia									
Normal (>=90)	4 (1.5)	4	1.1	2 (0.7)	2	0.5	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	3	2.0	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Ingrowing nail									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Onychomadesis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Acne									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Alopecia areata									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hyperhidrosis									
Normal (>=90)	0			1 (0.4)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Miliaria									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nail dystrophy									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cornification and dystrophic skin disorders									
Normal (>=90)	1 (0.4)	1	0.3	0			2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Actinic keratosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dermatitis papillaris capillitii									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperkeratosis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Punctate keratosis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cutaneous neoplasms benign									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	3	1.9
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Dermal cyst									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	3	1.9
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Angioedema and urticaria									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			2 (8.7)	2	7.0
Severe RI (15-<30)				0			0		
Urticaria									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			2	(8.7)	2 7.0
Severe RI (15-<30)				0			0		
Chronic spontaneous urticaria									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin and subcutaneous tissue disorders NEC									
Normal (>=90)	0			1	(0.4)	4 1.1	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Diabetic foot									
Normal (>=90)	0			1	(0.4)	3 0.8	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin ulcer									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Skin vascular abnormalities									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ecchymosis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haemorrhage subcutaneous									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Psychiatric disorders									
Normal (>=90)	19 (7.2)	22	6.3	13 (4.8)	16	4.4	10 (3.9)	11	3.2
Mild RI (60-<90)	3 (2.5)	5	3.2	9 (7.9)	11	7.4	4 (3.3)	4	2.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	2	11.0	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Sleep disorders and disturbances									
Normal (>=90)	6 (2.3)	6	1.7	6 (2.2)	6	1.6	2 (0.8)	2	0.6
Mild RI (60-<90)	0			3 (2.6)	3	2.0	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Insomnia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	6 (2.3)	6	1.7	4 (1.5)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Middle insomnia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abnormal dreams									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sleep disorder									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Anxiety disorders and symptoms									
Normal (>=90)	8 (3.0)	9	2.6	1 (0.4)	1	0.3	4 (1.5)	4	1.2
Mild RI (60-<90)	1 (0.8)	1	0.6	3 (2.6)	3	2.0	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Anxiety									
Normal (>=90)	6 (2.3)	7	2.0	1 (0.4)	1	0.3	2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Anxiety disorder due to a general medical condition									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Stress									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Generalised anxiety disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nervousness									
Normal (>=90)	2 (0.8)	2	0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post-traumatic stress disorder									
Normal (>=90)	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Depressed mood disorders and disturbances									
Normal (>=90)	4 (1.5)	4	1.1	5 (1.9)	5	1.4	5 (1.9)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Depressed mood									
Normal (>=90)	3 (1.1)	3	0.9	3 (1.1)	3	0.8	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Depression									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	5 (1.9)	5	1.4
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Anhedonia									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Major depression									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Adjustment disorders (incl subtypes)												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	2	(1.8)	2	1.3	0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Adjustment disorder with depressed mood												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Grief reaction												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Suicidal and self-injurious behaviours NEC												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				1	(0.9)	1	0.7	0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Suicidal ideation												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mood disorders and disturbances NEC									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	3	0.8	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Irritability									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mood altered									
Normal (>=90)	0			1 (0.4)	2	0.5	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mood swings									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Changes in physical activity									
Normal (>=90)	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Restlessness									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Psychiatric disorders NEC									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mental status changes									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Sexual dysfunctions, disturbances and gender identity disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Libido decreased									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vascular disorders									
Normal (>=90)	16 (6.0)	16	4.6	14 (5.2)	15	4.1	15 (5.8)	16	4.6
Mild RI (60-<90)	5 (4.2)	6	3.8	8 (7.0)	9	6.0	14 (11.7)	15	9.7
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	2	11.0	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vascular disorders NEC									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Aortic rupture									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hot flush									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aortic dilatation									
Normal (>=90)	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vascular hypertensive disorders									
Normal (>=90)	7 (2.6)	7	2.0	6 (2.2)	6	1.6	9 (3.5)	10	2.9
Mild RI (60-<90)	2 (1.7)	2	1.3	4 (3.5)	5	3.3	6 (5.0)	6	3.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertension									
Normal (>=90)	7 (2.6)	7	2.0	6 (2.2)	6	1.6	9 (3.5)	9	2.6
Mild RI (60-<90)	2 (1.7)	2	1.3	4 (3.5)	5	3.3	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertensive crisis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypertensive urgency									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aneurysms and artery dissections									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Aortic aneurysm									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Decreased and nonspecific blood pressure disorders and shock									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	4	1.1	2 (0.8)	2	0.6
Mild RI (60-<90)	2 (1.7)	3	1.9	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Hypotension									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Blood pressure inadequately controlled									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Orthostatic hypotension									
Normal (>=90)	0			1 (0.4)	2	0.5	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Shock									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vascular haemorrhagic disorders									
Normal (>=90)	0			2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Haematoma									
Normal (>=90)	0			2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Normal (>=90)	6 (2.3)	6	1.7	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	4 (3.3)	5	3.2
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Aortic arteriosclerosis									
Normal (>=90)	3 (1.1)	3	0.9	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Arteriosclerosis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral arterial occlusive disease									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral artery stenosis									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral coldness									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Peripheral venous disease									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			2 (1.7)	3	1.9
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Embolism and thrombosis									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Post thrombotic syndrome									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Deep vein thrombosis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vascular infections and inflammations									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Temporal arteritis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lymphatic vessel disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lymphoedema									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Venous varices									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Varicose vein									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Ear and labyrinth disorders									
Normal (>=90)	6 (2.3)	8	2.3	9 (3.3)	9	2.5	7 (2.7)	8	2.3
Mild RI (60-<90)	4 (3.3)	5	3.2	9 (7.9)	9	6.0	4 (3.3)	4	2.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.9)	1	4.6	2 (11.1)	2	11.0	1 (4.3)	2	7.0
Severe RI (15-<30)				0			0		
Aural disorders NEC									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			5 (4.4)	5	3.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Ear pain									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			4 (3.5)	4	2.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Ear pruritus									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Ear discomfort									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
External ear disorders (excl congenital)									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Cerumen impaction									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Excessive cerumen production									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Inner ear and VIIIth cranial nerve disorders									
Normal (>=90)	4 (1.5)	6	1.7	8 (3.0)	8	2.2	5 (1.9)	6	1.7
Mild RI (60-<90)	3 (2.5)	4	2.5	2 (1.8)	2	1.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vertigo									
Normal (>=90)	2 (0.8)	3	0.9	6 (2.2)	6	1.6	4 (1.5)	5	1.4
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Vertigo positional									
Normal (>=90)	0			2 (0.7)	2	0.5	1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Motion sickness									
Normal (>=90)	2 (0.8)	3	0.9	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Tinnitus									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	2 (1.7)	2	1.3	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Hearing disorders									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			2 (1.8)	2	1.3	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypoacusis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Deafness bilateral									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Deafness unilateral									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Mixed deafness									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Blood and lymphatic system disorders									
Normal (>=90)	7 (2.6)	7	2.0	9 (3.3)	9	2.5	4 (1.5)	4	1.2
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	3	2.0	6 (5.0)	7	4.5
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Anaemias nonhaemolytic and marrow depression									
Normal (>=90)	7 (2.6)	7	2.0	7 (2.6)	7	1.9	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	3	2.0	4 (3.3)	4	2.6
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Anaemia									
Normal (>=90)	3 (1.1)	3	0.9	6 (2.2)	6	1.6	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Pancytopenia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Iron deficiency anaemia									
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypochromic anaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Microcytic anaemia									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Normocytic anaemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Platelet disorders									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Thrombocytosis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
Normal (>=90)	0			1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Splenomegaly									
Normal (>=90)	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lymphadenopathy									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
White blood cell disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Leukocytosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lymphopenia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Normal (>=90)	7 (2.6)	8	2.3	5 (1.9)	5	1.4	6 (2.3)	6	1.7
Mild RI (60-<90)	6 (5.0)	8	5.1	3 (2.6)	3	2.0	5 (4.2)	6	3.9
Moderate RI (30-<60)	0			1 (5.6)	2	11.0	1 (4.3)	2	7.0
Severe RI (15-<30)				0			0		
Miscellaneous and site unspecified neoplasms malignant and unspecified									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Squamous cell carcinoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Nasal cavity cancer									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1	(5.6)	1 5.5	0		
Severe RI (15-<30)				0			0		
Keratinising squamous cell carcinoma of nasopharynx									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal neoplasms benign									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal tract adenoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Benign duodenal neoplasm									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Colon adenoma									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	1 (0.8)	2	1.3	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Leukaemias									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Myeloid leukaemia									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Chronic lymphocytic leukaemia									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lymphomas non-Hodgkin's unspecified histology									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal lymphoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cutaneous neoplasms benign									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Anogenital warts									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Melanocytic naevus									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Skeletal neoplasms benign									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Osteochondroma									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Soft tissue neoplasms benign									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Lipoma									
Normal (>=90)	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Breast neoplasms malignant and unspecified (incl nipple)									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Invasive ductal breast carcinoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Endocrine neoplasms benign									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pituitary tumour benign									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Endocrine neoplasms malignant and unspecified									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Neuroendocrine tumour									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal neoplasms malignant and unspecified									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	3 (2.5)	3	1.9	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Adenocarcinoma gastric									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Adenocarcinoma of colon									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastric cancer									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastric cancer stage IV									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal stromal tumour									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gastrointestinal submucosal tumour									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Oral neoplasm									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatobiliary neoplasms malignant and unspecified									
Normal (>=90)	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatocellular carcinoma									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metastases									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metastases to liver									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive neoplasms female benign									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Uterine leiomyoma									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive neoplasms female malignant and unspecified									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Uterine cancer									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive neoplasms male malignant and unspecified									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Prostate cancer									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			2	(1.7)	2 1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Skin neoplasms malignant and unspecified									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Basal cell carcinoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Hepatobiliary disorders									
Normal (>=90)	8 (3.0)	9	2.6	7 (2.6)	8	2.2	6 (2.3)	11	3.2
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	4	2.7	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hepatic and hepatobiliary disorders									
Normal (>=90)	4 (1.5)	4	1.1	5 (1.9)	6	1.6	6 (2.3)	7	2.0
Mild RI (60-<90)	2 (1.7)	2	1.3	2 (1.8)	2	1.3	3 (2.5)	3	1.9
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Portal vein thrombosis									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hepatic steatosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	3	0.8	3 (1.2)	3	0.9
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	2 (1.7)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatic cyst									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatic lesion									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Non-alcoholic steatohepatitis									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nonalcoholic fatty liver disease									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Drug-induced liver injury									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatic cirrhosis									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hepatomegaly									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Liver disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Portal hypertension									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gallbladder disorders									
Normal (>=90)	4	(1.5)	5 1.4	2	(0.7)	2 0.5	3	(1.2)	4 1.2
Mild RI (60-<90)	0			1	(0.9)	2 1.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cholecystitis chronic									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cholelithiasis									
Normal (>=90)	3 (1.1)	3	0.9	0			3 (1.2)	3	0.9
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Gallbladder polyp									
Normal (>=90)	2 (0.8)	2	0.6	2 (0.7)	2	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cholecystitis acute									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Endocrine disorders									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Thyroid gland disorders									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.8)	2	0.6
Mild RI (60-<90)	1 (0.8)	1	0.6	2 (1.8)	2	1.3	2 (1.7)	2	1.3
Moderate RI (30-<60)	1 (5.9)	1	4.6	1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Primary hyperthyroidism									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			1 (5.6)	1	5.5	0		
Severe RI (15-<30)				0			0		
Hypothyroidism									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Thyroid cyst									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Autoimmune thyroiditis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severe RI (15-<30)				0			0		
Goitre									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Silent thyroiditis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (5.9)	1	4.6	0			0		
Severe RI (15-<30)				0			0		
Thyroid mass									
Normal (>=90)	0			0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive system and breast disorders									
Normal (>=90)	9 (3.4)	14	4.0	11 (4.1)	11	3.0	8 (3.1)	9	2.6
Mild RI (60-<90)	6 (5.0)	6	3.8	1 (0.9)	1	0.7	1 (0.8)	2	1.3
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Menstrual cycle and uterine bleeding disorders									
Normal (>=90)	2 (0.8)	2	0.6	3 (1.1)	3	0.8	1 (0.4)	2	0.6
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Dysmenorrhoea									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Metrorrhagia									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Oligomenorrhoea									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Menorrhagia									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Menstruation irregular									
Normal (>=90)	1	(0.4)	1 0.3	0			1	(0.4)	2 0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Vulvovaginal disorders (excl infections and inflammations)									
Normal (>=90)	1	(0.4)	1 0.3	3	(1.1)	3 0.8	1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulva cyst									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulval disorder									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulvovaginal pruritus									
Normal (>=90)	0			1	(0.4)	1 0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vaginal disorder									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Severe RI (15-<30)				0			0		
Vaginal haemorrhage									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Vulvovaginal dryness									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Uterine, pelvic and broad ligament disorders									
Normal (>=90)	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Uterine polyp									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(0.9)	1 0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Adenomyosis									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Endometriosis												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Sexual function and fertility disorders												
Normal (>=90)	2	(0.8)	2	0.6	2	(0.7)	2	0.5	1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Erectile dysfunction												
Normal (>=90)	2	(0.8)	2	0.6	2	(0.7)	2	0.5	1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Breast disorders												
Normal (>=90)	0				1	(0.4)	1	0.3	1	(0.4)	1	0.3
Mild RI (60-<90)	2	(1.7)	2	1.3	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Breast mass												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severe RI (15-<30)					0				0			
Breast cyst												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Breast pain												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Menopause related conditions												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Atrophic vulvovaginitis												
Normal (>=90)	0				1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				1	(0.8)	1	0.6
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Reproductive tract disorders NEC												
Normal (>=90)	2	(0.8)	2	0.6	1	(0.4)	1	0.3	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pruritus genital									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pelvic pain									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Male reproductive tract infections and inflammations									
Normal (>=90)	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Balanoposthitis									
Normal (>=90)	1 (0.4)	1	0.3	0			0		
Mild RI (60-<90)	2 (1.7)	2	1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Prostatitis									
Normal (>=90)	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Ovarian and fallopian tube disorders												
Normal (>=90)	2	(0.8)	2	0.6	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Haemorrhagic ovarian cyst												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Ovarian cyst												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Penile and scrotal disorders (excl infections and inflammations)												
Normal (>=90)	1	(0.4)	2	0.6	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Penile erosion												
Normal (>=90)	1	(0.4)	1	0.3	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Peyronie's disease									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Prostatic disorders (excl infections and inflammations)									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	2	(1.7)	2 1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Benign prostatic hyperplasia									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	2	(1.7)	2 1.3	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Testicular and epididymal disorders									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Testicular disorder									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Immune system disorders									
Normal (>=90)	3 (1.1)	3	0.9	5 (1.9)	5	1.4	5 (1.9)	6	1.7
Mild RI (60-<90)	3 (2.5)	3	1.9	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Allergic conditions									
Normal (>=90)	3 (1.1)	3	0.9	5 (1.9)	5	1.4	5 (1.9)	6	1.7
Mild RI (60-<90)	2 (1.7)	2	1.3	1 (0.9)	1	0.7	1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Seasonal allergy									
Normal (>=90)	1 (0.4)	1	0.3	3 (1.1)	3	0.8	4 (1.5)	5	1.4
Mild RI (60-<90)	1 (0.8)	1	0.6	1 (0.9)	1	0.7	0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Allergy to arthropod sting									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Hypersensitivity									
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Allergy to chemicals									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Drug hypersensitivity									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Multiple allergies									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Immune disorders NEC									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Immunisation reaction									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Surgical and medical procedures									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Mild RI (60-<90)	2 (1.7)	2	1.3	0			3 (2.5)	4	2.6
Moderate RI (30-<60)	0			0			1 (4.3)	1	3.5
Severe RI (15-<30)				0			0		
Endocrine gland therapeutic procedures									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Thyroidectomy									
Normal (>=90)	0			1 (0.4)	1	0.3	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone and joint therapeutic procedures									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			1 (0.8)	1	0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Bone graft									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (0.8)	1	0.6	0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Joint injection									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac therapeutic procedures									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Cardiac pacemaker replacement									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Eye therapeutic procedures									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Cataract operation									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			1	(4.3)	1 3.5
Severe RI (15-<30)				0			0		
Head and neck therapeutic procedures									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(0.8)	1 0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Tooth extraction												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(0.8)	1	0.6	0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Male genital tract therapeutic procedures												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Sperm aspiration												
Normal (>=90)	0				0				1	(0.4)	1	0.3
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Therapeutic procedures and supportive care NEC												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				0				3	(2.5)	3	1.9
Moderate RI (30-<60)	0				0				0			
Severe RI (15-<30)					0				0			
Cyst removal												
Normal (>=90)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Nerve block									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Stent placement									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(0.8)	1 0.6
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Congenital, familial and genetic disorders									
Normal (>=90)	1	(0.4)	1 0.3	0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Reproductive tract and breast disorders congenital									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Phimosis									
Normal (>=90)	0			0			2	(0.8)	2 0.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Respiratory disorders congenital									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Laryngeal web									
Normal (>=90)	1	(0.4)	1 0.3	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Pregnancy, puerperium and perinatal conditions									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Abortions and stillbirth									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Abortion spontaneous									
Normal (>=90)	0			0			1	(0.4)	1 0.3
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Social circumstances									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Economic and housing issues									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		
Stress at work									
Normal (>=90)	2	(0.8)	2 0.6	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Severe RI (15-<30)				0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

29 Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Normal (>=90)	73	100.2			140	194.2			78	110.1		
Mild RI (60-<90)	26	34.6			58	79.4			23	31.8		
Moderate RI (30-<60)	1	1.4			1	1.4						
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Normal (>=90)	64	(87.7)	383	382.3	121	(86.4)	618	318.3	65	(83.3)	195	177.2
Mild RI (60-<90)	17	(65.4)	90	260.0	49	(84.5)	214	269.4	15	(65.2)	40	125.9
Moderate RI (30-<60)	1	(100)	10	703.8	1	(100)	2	140.8				
Serious												
Yes												
Normal (>=90)	6	(8.2)	9	9.0	5	(3.6)	5	2.6	5	(6.4)	5	4.5
Mild RI (60-<90)	1	(3.8)	1	2.9	5	(8.6)	7	8.8	2	(8.7)	2	6.3
Moderate RI (30-<60)	0				0							
No												
Normal (>=90)	64	(87.7)	374	373.3	121	(86.4)	613	315.7	64	(82.1)	190	172.6
Mild RI (60-<90)	17	(65.4)	89	257.2	48	(82.8)	207	260.6	14	(60.9)	38	119.6
Moderate RI (30-<60)	1	(100)	10	703.8	1	(100)	2	140.8				
Severity												
Severe												
Normal (>=90)	2	(2.7)	2	2.0	0				3	(3.8)	3	2.7
Mild RI (60-<90)	1	(3.8)	1	2.9	3	(5.2)	4	5.0	2	(8.7)	2	6.3
Moderate RI (30-<60)	0				0							

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severity									
Moderate									
Normal (>=90)	13 (17.8)	52	51.9	22 (15.7)	37	19.1	11 (14.1)	13	11.8
Mild RI (60-<90)	1 (3.8)	11	31.8	3 (5.2)	5	6.3	0		
Moderate RI (30-<60)	0			0					
Mild									
Normal (>=90)	61 (83.6)	329	328.4	119 (85.0)	581	299.2	62 (79.5)	179	162.6
Mild RI (60-<90)	17 (65.4)	78	225.4	48 (82.8)	205	258.1	14 (60.9)	38	119.6
Moderate RI (30-<60)	1 (100)	10	703.8	1 (100)	2	140.8			
Relationship to trial product									
Missing									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0					
Probable									
Normal (>=90)	19 (26.0)	50	49.9	39 (27.9)	119	61.3	8 (10.3)	13	11.8
Mild RI (60-<90)	6 (23.1)	11	31.8	15 (25.9)	38	47.8	2 (8.7)	3	9.4
Moderate RI (30-<60)	0			1 (100)	1	70.4			
Possible									
Normal (>=90)	42 (57.5)	163	162.7	60 (42.9)	148	76.2	7 (9.0)	12	10.9
Mild RI (60-<90)	12 (46.2)	20	57.8	24 (41.4)	58	73.0	3 (13.0)	5	15.7
Moderate RI (30-<60)	1 (100)	7	492.6	0					
Unlikely									
Normal (>=90)	58 (79.5)	170	169.7	108 (77.1)	350	180.2	60 (76.9)	170	154.4
Mild RI (60-<90)	14 (53.8)	59	170.5	43 (74.1)	118	148.6	14 (60.9)	32	100.7
Moderate RI (30-<60)	1 (100)	3	211.1	1 (100)	1	70.4			

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by renal function at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Outcome									
Recovered									
Normal (>=90)	61 (83.6)	332	331.4	117 (83.6)	544	280.2	60 (76.9)	152	138.1
Mild RI (60-<90)	16 (61.5)	67	193.6	46 (79.3)	183	230.4	15 (65.2)	34	107.0
Moderate RI (30-<60)	1 (100)	10	703.8	1 (100)	2	140.8			
Recovering									
Normal (>=90)	8 (11.0)	14	14.0	13 (9.3)	17	8.8	3 (3.8)	3	2.7
Mild RI (60-<90)	1 (3.8)	2	5.8	3 (5.2)	4	5.0	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0					
Not Recovered									
Normal (>=90)	27 (37.0)	37	36.9	35 (25.0)	57	29.4	24 (30.8)	40	36.3
Mild RI (60-<90)	8 (30.8)	21	60.7	19 (32.8)	27	34.0	2 (8.7)	4	12.6
Moderate RI (30-<60)	0			0					
Leading to									
Permanent treatment discontinuation									
Normal (>=90)	1 (1.4)	4	4.0	1 (0.7)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	2 (7.7)	2	5.8	4 (6.9)	7	8.8	0		
Moderate RI (30-<60)	0			0					
Temporary interruption of trial product									
Normal (>=90)	5 (6.8)	6	6.0	8 (5.7)	11	5.7	3 (3.8)	3	2.7
Mild RI (60-<90)	2 (7.7)	3	8.7	6 (10.3)	15	18.9	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0					
Dose reduction of trial product									
Normal (>=90)	2 (2.7)	2	2.0	12 (8.6)	17	8.8	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0					

Adverse events with onset prior to randomisation are not included.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

30 Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Normal (>=90)	73		100.2		140		194.2		78		110.1	
Mild RI (60-<90)	26		34.6		58		79.4		23		31.8	
Moderate RI (30-<60)	1		1.4		1		1.4		0			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Normal (>=90)	64	(87.7)	383	382.3	121	(86.4)	618	318.3	65	(83.3)	195	177.2
Mild RI (60-<90)	17	(65.4)	90	260.0	49	(84.5)	214	269.4	15	(65.2)	40	125.9
Moderate RI (30-<60)	1	(100)	10	703.8	1	(100)	2	140.8	0			
Gastrointestinal disorders												
Normal (>=90)	49	(67.1)	215	214.6	81	(57.9)	254	130.8	23	(29.5)	33	30.0
Mild RI (60-<90)	14	(53.8)	34	98.2	36	(62.1)	88	110.8	7	(30.4)	10	31.5
Moderate RI (30-<60)	1	(100)	7	492.6	1	(100)	1	70.4	0			
Gastrointestinal motility and defaecation conditions												
Normal (>=90)	30	(41.1)	70	69.9	55	(39.3)	86	44.3	6	(7.7)	6	5.5
Mild RI (60-<90)	10	(38.5)	12	34.7	22	(37.9)	32	40.3	3	(13.0)	3	9.4
Moderate RI (30-<60)	1	(100)	2	140.8	1	(100)	1	70.4	0			
Constipation												
Normal (>=90)	14	(19.2)	17	17.0	37	(26.4)	41	21.1	1	(1.3)	1	0.9
Mild RI (60-<90)	5	(19.2)	5	14.4	14	(24.1)	18	22.7	2	(8.7)	2	6.3
Moderate RI (30-<60)	0				1	(100)	1	70.4	0			
Diarrhoea												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	18 (24.7)	52	51.9	24 (17.1)	40	20.6	5 (6.4)	5	4.5
Mild RI (60-<90)	3 (11.5)	5	14.4	8 (13.8)	12	15.1	1 (4.3)	1	3.1
Moderate RI (30-<60)	1 (100)	2	140.8	0			0		
Gastrooesophageal reflux disease									
Normal (>=90)	0			4 (2.9)	4	2.1	0		
Mild RI (60-<90)	2 (7.7)	2	5.8	2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal motility disorder									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Irritable bowel syndrome									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal signs and symptoms									
Normal (>=90)	31 (42.5)	131	130.8	50 (35.7)	129	66.4	6 (7.7)	11	10.0
Mild RI (60-<90)	7 (26.9)	16	46.2	21 (36.2)	40	50.4	5 (21.7)	6	18.9
Moderate RI (30-<60)	1 (100)	4	281.5	0			0		
Nausea									
Normal (>=90)	13 (17.8)	21	21.0	27 (19.3)	56	28.8	2 (2.6)	2	1.8
Mild RI (60-<90)	5 (19.2)	6	17.3	8 (13.8)	10	12.6	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Vomiting									
Normal (>=90)	7 (9.6)	31	30.9	13 (9.3)	22	11.3	1 (1.3)	1	0.9
Mild RI (60-<90)	3 (11.5)	3	8.7	4 (6.9)	7	8.8	1 (4.3)	1	3.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Abdominal pain									
Normal (>=90)	2 (2.7)	2	2.0	7 (5.0)	10	5.1	0		
Mild RI (60-<90)	1 (3.8)	2	5.8	5 (8.6)	6	7.6	0		
Moderate RI (30-<60)	0			0			0		
Abdominal discomfort									
Normal (>=90)	9 (12.3)	10	10.0	8 (5.7)	12	6.2	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	4	5.0	1 (4.3)	1	3.1
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Dyspepsia									
Normal (>=90)	4 (5.5)	15	15.0	5 (3.6)	10	5.1	1 (1.3)	4	3.6
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	4	5.0	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Abdominal pain upper									
Normal (>=90)	3 (4.1)	5	5.0	8 (5.7)	11	5.7	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Abdominal distension									
Normal (>=90)	6 (8.2)	7	7.0	4 (2.9)	5	2.6	1 (1.3)	2	1.8
Mild RI (60-<90)	1 (3.8)	1	2.9	3 (5.2)	3	3.8	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Eructation									
Normal (>=90)	2 (2.7)	19	19.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Faeces soft									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Faeces hard									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Flatulence									
Normal (>=90)	1 (1.4)	18	18.0	0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Abdominal tenderness									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Abdominal pain lower									
Normal (>=90)	1 (1.4)	2	2.0	0			1 (1.3)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Epigastric discomfort									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Dental and gingival conditions									
Normal (>=90)	4 (5.5)	4	4.0	9 (6.4)	10	5.1	5 (6.4)	5	4.5
Mild RI (60-<90)	2 (7.7)	2	5.8	5 (8.6)	5	6.3	1 (4.3)	1	3.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Dental caries									
Normal (>=90)	2 (2.7)	2	2.0	7 (5.0)	8	4.1	4 (5.1)	4	3.6
Mild RI (60-<90)	2 (7.7)	2	5.8	4 (6.9)	4	5.0	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Toothache									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Tooth impacted									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dental cyst									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal inflammatory conditions									
Normal (>=90)	1 (1.4)	1	1.0	6 (4.3)	7	3.6	5 (6.4)	5	4.5
Mild RI (60-<90)	0			4 (6.9)	4	5.0	0		
Moderate RI (30-<60)	0			0			0		
Gastritis									
Normal (>=90)	0			1 (0.7)	1	0.5	3 (3.8)	3	2.7
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Enterocolitis									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Colitis ischaemic									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Chronic gastritis									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Colitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Enteritis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal conditions NEC									
Normal (>=90)	4 (5.5)	4	4.0	9 (6.4)	11	5.7	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Food poisoning									
Normal (>=90)	0			2 (1.4)	2	1.0	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal disorder									
Normal (>=90)	2 (2.7)	2	2.0	4 (2.9)	6	3.1	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastric disorder									
Normal (>=90)	2 (2.7)	2	2.0	3 (2.1)	3	1.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Barrett's oesophagus									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Benign neoplasms gastrointestinal									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	4	2.1	2 (2.6)	2	1.8
Mild RI (60-<90)	2 (7.7)	2	5.8	3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Large intestine polyp									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	1	2.9	2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Gastric polyps									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Rectal polyp									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(3.8)	1 2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Oral soft tissue conditions									
Normal (>=90)	0			2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Angular cheilitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Stomatitis									
Normal (>=90)	0			2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal ulceration and perforation									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			1	(1.7)	2 2.5	0		
Moderate RI (30-<60)	0			0			0		
Erosive duodenitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Gastritis erosive									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal haemorrhages NEC									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Anal haemorrhage									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Mallory-Weiss syndrome									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Anal and rectal conditions NEC									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Anal fissure									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Diverticular disorders									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Diverticulum intestinal									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal vascular conditions									
Normal (>=90)	2 (2.7)	2	2.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Haemorrhoids									
Normal (>=90)	2 (2.7)	2	2.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal stenosis and obstruction									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Intestinal obstruction									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Salivary gland conditions									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Parotid gland enlargement									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Investigations									
Normal (>=90)	7 (9.6)	9	9.0	11 (7.9)	14	7.2	7 (9.0)	9	8.2
Mild RI (60-<90)	6 (23.1)	7	20.2	4 (6.9)	5	6.3	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			1 (100)	1	70.4	0		
Enzyme investigations NEC									
Normal (>=90)	3 (4.1)	3	3.0	5 (3.6)	6	3.1	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			1 (100)	1	70.4	0		
Blood creatine phosphokinase increased									
Normal (>=90)	3 (4.1)	3	3.0	5 (3.6)	6	3.1	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			1 (100)	1	70.4	0		
Cardiac and vascular investigations (excl enzyme tests)									
Normal (>=90)	2 (2.7)	2	2.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Blood pressure decreased									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0				0			
Electrocardiogram QRS complex prolonged												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Electrocardiogram QT prolonged												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Gastrointestinal investigations												
Normal (>=90)	1	(1.4)	1	1.0	3	(2.1)	4	2.1	0			
Mild RI (60-<90)	4	(15.4)	4	11.6	1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			
Lipase increased												
Normal (>=90)	0				3	(2.1)	3	1.5	0			
Mild RI (60-<90)	3	(11.5)	3	8.7	1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			
Amylase increased												
Normal (>=90)	1	(1.4)	1	1.0	1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Occult blood positive												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	0				0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Haematology investigations (incl blood groups)												
Normal (>=90)	1	(1.4)	2	2.0	0				0			
Mild RI (60-<90)	0				1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			
Haemoglobin decreased												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	0				1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			
Lymphocyte count decreased												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
White blood cell count increased												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Physical examination and organ system status topics												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			
Weight decreased												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	1	(1.7)	1	1.3	0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hepatobiliary investigations									
Normal (>=90)	0			2 (1.4)	2	1.0	5 (6.4)	5	4.5
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Aspartate aminotransferase increased									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Liver function test increased									
Normal (>=90)	0			1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Alanine aminotransferase increased									
Normal (>=90)	0			0			2 (2.6)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Blood bilirubin increased									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Endocrine investigations (incl sex hormones)									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Blood thyroid stimulating hormone decreased									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Lipid analyses									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Blood triglycerides increased									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Metabolic, nutritional and blood gas investigations									
Normal (>=90)	0			0			2	(2.6)	2 1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Blood uric acid increased									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Glycosylated haemoglobin increased									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Protein and chemistry analyses NEC												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				1	(4.3)	1	3.1
Moderate RI (30-<60)	0				0				0			
C-reactive protein increased												
Normal (>=90)	1	(1.4)	1	1.0	0				0			
Mild RI (60-<90)	0				0				1	(4.3)	1	3.1
Moderate RI (30-<60)	0				0				0			
Water, electrolyte and mineral investigations												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	0				0			
Moderate RI (30-<60)	0				0				0			
Blood potassium increased												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	0				0			
Moderate RI (30-<60)	0				0				0			
Infections and infestations												
Normal (>=90)	35	(47.9)	49	48.9	60	(42.9)	117	60.3	29	(37.2)	43	39.1
Mild RI (60-<90)	7	(26.9)	15	43.3	20	(34.5)	36	45.3	6	(26.1)	10	31.5
Moderate RI (30-<60)	0				0				0			
Infections - pathogen unspecified												
Normal (>=90)	32	(43.8)	44	43.9	53	(37.9)	100	51.5	28	(35.9)	41	37.2
Mild RI (60-<90)	7	(26.9)	14	40.5	18	(31.0)	32	40.3	6	(26.1)	10	31.5
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nasopharyngitis									
Normal (>=90)	17 (23.3)	23	23.0	38 (27.1)	58	29.9	14 (17.9)	18	16.4
Mild RI (60-<90)	7 (26.9)	13	37.6	15 (25.9)	23	29.0	4 (17.4)	6	18.9
Moderate RI (30-<60)	0			0			0		
Gastroenteritis									
Normal (>=90)	7 (9.6)	8	8.0	9 (6.4)	11	5.7	1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Bronchitis									
Normal (>=90)	3 (4.1)	3	3.0	6 (4.3)	9	4.6	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Pharyngitis									
Normal (>=90)	3 (4.1)	3	3.0	2 (1.4)	3	1.5	3 (3.8)	4	3.6
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Conjunctivitis									
Normal (>=90)	0			1 (0.7)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Tonsillitis									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	2	6.3
Moderate RI (30-<60)	0			0			0		
Cystitis									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	1 (1.3)	2	1.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Diverticulitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Pyelonephritis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Pyelonephritis acute									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Urethritis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Rhinitis									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Acute sinusitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Enteritis infectious									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Folliculitis									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gingivitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hordeolum									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Pelvic inflammatory disease									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Sinusitis									
Normal (>=90)	0			1 (0.7)	1	0.5	3 (3.8)	3	2.7
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Urinary tract infection									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	3	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Periodontitis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Pyoderma									
Normal (>=90)	0			0			1 (1.3)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Upper respiratory tract infection									
Normal (>=90)	0			0			2 (2.6)	3	2.7
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Vaginal infection									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Viral infectious disorders									
Normal (>=90)	4 (5.5)	4	4.0	11 (7.9)	11	5.7	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	2 (3.4)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Influenza									
Normal (>=90)	2 (2.7)	2	2.0	6 (4.3)	6	3.1	1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Herpes zoster									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Gastroenteritis viral									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Herpes simplex									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Infectious mononucleosis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Bacterial infectious disorders									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	4	2.1	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Alpha haemolytic streptococcal infection									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Cellulitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Erysipelas									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Furuncle									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Helicobacter infection									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Fungal infectious disorders									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Tinea pedis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Vulvovaginal candidiasis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Musculoskeletal and connective tissue disorders									
Normal (>=90)	18 (24.7)	23	23.0	31 (22.1)	39	20.1	22 (28.2)	32	29.1
Mild RI (60-<90)	6 (23.1)	11	31.8	12 (20.7)	13	16.4	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Musculoskeletal and connective tissue disorders NEC									
Normal (>=90)	8 (11.0)	10	10.0	16 (11.4)	17	8.8	11 (14.1)	13	11.8
Mild RI (60-<90)	2 (7.7)	4	11.6	6 (10.3)	6	7.6	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Back pain									
Normal (>=90)	6 (8.2)	8	8.0	14 (10.0)	15	7.7	7 (9.0)	9	8.2
Mild RI (60-<90)	2 (7.7)	4	11.6	5 (8.6)	5	6.3	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Pain in extremity									
Normal (>=90)	1 (1.4)	1	1.0	0			2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Musculoskeletal discomfort									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Neck pain									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Musculoskeletal pain									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Musculoskeletal stiffness									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Joint disorders									
Normal (>=90)	11 (15.1)	11	11.0	10 (7.1)	10	5.1	11 (14.1)	16	14.5
Mild RI (60-<90)	4 (15.4)	6	17.3	3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Arthralgia									
Normal (>=90)	6 (8.2)	6	6.0	4 (2.9)	4	2.1	6 (7.7)	9	8.2
Mild RI (60-<90)	3 (11.5)	4	11.6	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Periarthritis									
Normal (>=90)	0			3 (2.1)	3	1.5	1 (1.3)	1	0.9
Mild RI (60-<90)	2 (7.7)	2	5.8	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Osteoarthritis									
Normal (>=90)	2 (2.7)	2	2.0	1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Rotator cuff syndrome									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Spinal osteoarthritis									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Arthritis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Articular calcification									
Normal (>=90)	0			0			1 (1.3)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Muscle disorders									
Normal (>=90)	0			6 (4.3)	6	3.1	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Myalgia									
Normal (>=90)	0			3 (2.1)	3	1.5	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Muscle spasms									
Normal (>=90)	0			2 (1.4)	2	1.0	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Fibromyalgia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Rhabdomyolysis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Intervertebral disc protrusion									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Spinal stenosis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Tendon, ligament and cartilage disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	4	2.1	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Tendonitis									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Trigger finger									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Synovial and bursal disorders									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Bursitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Synovitis									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Nervous system disorders									
Normal (>=90)	5 (6.8)	8	8.0	25 (17.9)	34	17.5	5 (6.4)	5	4.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	3 (11.5)	3	8.7	10 (17.2)	18	22.7	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Neurological disorders NEC									
Normal (>=90)	4 (5.5)	6	6.0	15 (10.7)	20	10.3	2 (2.6)	2	1.8
Mild RI (60-<90)	2 (7.7)	2	5.8	7 (12.1)	13	16.4	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Dizziness									
Normal (>=90)	3 (4.1)	5	5.0	9 (6.4)	10	5.1	0		
Mild RI (60-<90)	0			5 (8.6)	9	11.3	0		
Moderate RI (30-<60)	0			0			0		
Hypoaesthesia									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	4	2.1	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Dizziness postural									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Dysgeusia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Neurological symptom									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dysaesthesia									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Neuralgia									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Paraesthesia									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Somnolence									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Taste disorder									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Intercostal neuralgia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Sensory loss									
Normal (>=90)	0			0			1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Headaches									
Normal (>=90)	1 (1.4)	1	1.0	7 (5.0)	9	4.6	3 (3.8)	3	2.7
Mild RI (60-<90)	1 (3.8)	1	2.9	3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Headache									
Normal (>=90)	1 (1.4)	1	1.0	7 (5.0)	9	4.6	3 (3.8)	3	2.7
Mild RI (60-<90)	1 (3.8)	1	2.9	3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Spinal cord and nerve root disorders									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Sciatica									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Central nervous system vascular disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Lacunar infarction									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Moderate RI (30-<60)	0				0				0			
Cranial nerve disorders (excl neoplasms)												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Parosmia												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Neuromuscular disorders												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Autonomic nervous system imbalance												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Peripheral neuropathies												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Carpal tunnel syndrome												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolism and nutrition disorders									
Normal (>=90)	5 (6.8)	5	5.0	15 (10.7)	16	8.2	7 (9.0)	9	8.2
Mild RI (60-<90)	1 (3.8)	1	2.9	8 (13.8)	8	10.1	1 (4.3)	2	6.3
Moderate RI (30-<60)	0			0			0		
Appetite and general nutritional disorders									
Normal (>=90)	4 (5.5)	4	4.0	7 (5.0)	7	3.6	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	6 (10.3)	6	7.6	0		
Moderate RI (30-<60)	0			0			0		
Decreased appetite									
Normal (>=90)	4 (5.5)	4	4.0	7 (5.0)	7	3.6	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	6 (10.3)	6	7.6	0		
Moderate RI (30-<60)	0			0			0		
Purine and pyrimidine metabolism disorders									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	3 (3.8)	3	2.7
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	2	6.3
Moderate RI (30-<60)	0			0			0		
Gout									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	2	6.3
Moderate RI (30-<60)	0			0			0		
Hyperuricaemia									
Normal (>=90)	0			2 (1.4)	2	1.0	3 (3.8)	3	2.7
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lipid metabolism disorders									
Normal (>=90)	0			1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Dyslipidaemia									
Normal (>=90)	0			1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Glucose metabolism disorders (incl diabetes mellitus)									
Normal (>=90)	0			2 (1.4)	3	1.5	3 (3.8)	4	3.6
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Diabetes mellitus									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Type 2 diabetes mellitus									
Normal (>=90)	0			1 (0.7)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Glucose tolerance impaired									
Normal (>=90)	0			0			1 (1.3)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Electrolyte and fluid balance conditions									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dehydration									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Metabolism disorders NEC									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hypercreatininaemia									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Normal (>=90)	8 (11.0)	11	11.0	17 (12.1)	18	9.3	11 (14.1)	17	15.4
Mild RI (60-<90)	1 (3.8)	1	2.9	7 (12.1)	9	11.3	2 (8.7)	2	6.3
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Respiratory tract signs and symptoms									
Normal (>=90)	4 (5.5)	5	5.0	11 (7.9)	11	5.7	9 (11.5)	13	11.8
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	6	7.6	2 (8.7)	2	6.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Upper respiratory tract inflammation									
Normal (>=90)	3 (4.1)	4	4.0	7 (5.0)	7	3.6	8 (10.3)	12	10.9
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	6	7.6	1 (4.3)	1	3.1
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Oropharyngeal pain									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Hiccups									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Rhinorrhoea									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Upper respiratory tract disorders (excl infections)									
Normal (>=90)	2 (2.7)	2	2.0	4 (2.9)	4	2.1	1 (1.3)	2	1.8
Mild RI (60-<90)	0			3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Rhinitis allergic									
Normal (>=90)	1 (1.4)	1	1.0	4 (2.9)	4	2.1	1 (1.3)	2	1.8
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Epistaxis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Vasomotor rhinitis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Respiratory disorders NEC									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Cough									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dyspnoea									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Bronchial disorders (excl neoplasms)									
Normal (>=90)	3 (4.1)	3	3.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Asthma									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Cough variant asthma									
Normal (>=90)	2 (2.7)	2	2.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Skin and subcutaneous tissue disorders									
Normal (>=90)	9 (12.3)	15	15.0	20 (14.3)	25	12.9	9 (11.5)	12	10.9
Mild RI (60-<90)	4 (15.4)	7	20.2	4 (6.9)	5	6.3	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Epidermal and dermal conditions									
Normal (>=90)	8 (11.0)	11	11.0	13 (9.3)	14	7.2	6 (7.7)	8	7.3
Mild RI (60-<90)	2 (7.7)	2	5.8	4 (6.9)	5	6.3	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Eczema									
Normal (>=90)	4 (5.5)	4	4.0	3 (2.1)	3	1.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Eczema asteatotic									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Dermatitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	2	2.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Pruritus									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	2 (2.6)	3	2.7
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dermatitis atopic									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dermatitis contact									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		
Dyshidrotic eczema									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Erythema									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Rash									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Stasis dermatitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Drug eruption									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dry skin									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Pain of skin									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Rash pruritic									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Seborrhoeic dermatitis									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Xanthelasma									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Skin appendage conditions									
Normal (>=90)	2 (2.7)	2	2.0	7 (5.0)	7	3.6	2 (2.6)	2	1.8
Mild RI (60-<90)	2 (7.7)	2	5.8	0			0		
Moderate RI (30-<60)	0			0			0		
Alopecia									
Normal (>=90)	2 (2.7)	2	2.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Alopecia areata									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Acne									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Ingrowing nail									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Miliaria									
Normal (>=90)	0			1 (0.7)	1	0.5	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Angioedema and urticaria									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	2 (2.7)	2	2.0	2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	2	5.8	0			0		
Moderate RI (30-<60)	0			0			0		
Urticaria									
Normal (>=90)	2 (2.7)	2	2.0	2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	2	5.8	0			0		
Moderate RI (30-<60)	0			0			0		
Cornification and dystrophic skin disorders									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Hyperkeratosis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Xeroderma									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Injury, poisoning and procedural complications									
Normal (>=90)	12 (16.4)	16	16.0	22 (15.7)	22	11.3	8 (10.3)	9	8.2
Mild RI (60-<90)	2 (7.7)	2	5.8	3 (5.2)	4	5.0	4 (17.4)	5	15.7
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Injuries NEC									
Normal (>=90)	5 (6.8)	9	9.0	14 (10.0)	14	7.2	6 (7.7)	6	5.5
Mild RI (60-<90)	0			3 (5.2)	4	5.0	3 (13.0)	4	12.6
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Ligament sprain									
Normal (>=90)	3 (4.1)	4	4.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	2	2.5	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Contusion									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Arthropod sting									
Normal (>=90)	0			3 (2.1)	3	1.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Post-traumatic neck syndrome									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Tendon rupture									
Normal (>=90)	0			2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Arthropod bite									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Epicondylitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Limb injury									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Subcutaneous haematoma									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Tooth fracture									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Limb crushing injury									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Muscle contusion									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Muscle strain									
Normal (>=90)	1 (1.4)	2	2.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Road traffic accident									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Skin laceration									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Subdural haematoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Bone and joint injuries									
Normal (>=90)	4 (5.5)	4	4.0	4 (2.9)	4	2.1	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Ankle fracture									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Meniscus injury									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Radius fracture									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Rib fracture									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Fracture									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Joint injury									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Injuries by physical agents									
Normal (>=90)	2 (2.7)	2	2.0	2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	1	2.9	0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Heat stroke									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Thermal burn									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Heat illness									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Medication errors and other product use errors and issues									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Accidental overdose									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Product administration error									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Eye disorders									
Normal (>=90)	5 (6.8)	6	6.0	13 (9.3)	15	7.7	5 (6.4)	6	5.5
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	4	5.0	2 (8.7)	2	6.3
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retina, choroid and vitreous haemorrhages and vascular disorders									
Normal (>=90)	2 (2.7)	3	3.0	5 (3.6)	5	2.6	2 (2.6)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Diabetic retinopathy									
Normal (>=90)	1 (1.4)	2	2.0	3 (2.1)	3	1.5	2 (2.6)	2	1.8
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Retinal exudates									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Retinal haemorrhage									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Retinopathy									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Anterior eye structural change, deposit and degeneration									
Normal (>=90)	0			2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Cataract									
Normal (>=90)	0			2	(1.4)	2 1.0	1	(1.3)	1 0.9
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Vision disorders									
Normal (>=90)	0			4	(2.9)	4 2.1	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Amblyopia									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Optic nerve disorder									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Presbyopia									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Visual acuity reduced									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Glaucoma and ocular hypertension									
Normal (>=90)	0			0			1	(1.3)	1 0.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Glaucoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Open angle glaucoma									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Ocular haemorrhages and vascular disorders NEC									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Optic disc haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Conjunctival haemorrhage									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Normal (>=90)	2 (2.7)	2	2.0	0			1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Retinal tear									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Macular fibrosis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Rhegmatogenous retinal detachment									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Ocular infections, irritations and inflammations									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Conjunctivitis allergic									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Ocular hyperaemia									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Eye disorders NEC									
Normal (>=90)	0			1 (0.7)	2	1.0	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Lacrimal disorder									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Lacrimation increased									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Dry eye									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
General disorders and administration site conditions									
Normal (>=90)	3 (4.1)	5	5.0	13 (9.3)	31	16.0	2 (2.6)	2	1.8
Mild RI (60-<90)	0			3 (5.2)	4	5.0	0		
Moderate RI (30-<60)	0			0			0		
General system disorders NEC									
Normal (>=90)	2 (2.7)	4	4.0	9 (6.4)	15	7.7	1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	3	3.8	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Moderate RI (30-<60)	0			0			0		
Malaise									
Normal (>=90)	1	(1.4)	1 1.0	4	(2.9)	7 3.6	0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Fatigue									
Normal (>=90)	0			2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Pain									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Feeling abnormal									
Normal (>=90)	0			2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Influenza like illness									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Non-cardiac chest pain									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Oedema peripheral									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Thirst									
Normal (>=90)	0			1	(0.7)	1 0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hangover									
Normal (>=90)	1	(1.4)	3 3.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hunger									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Administration site reactions									
Normal (>=90)	0			3	(2.1)	14 7.2	0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Injection site discomfort									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1	(1.7)	1 1.3	0		
Moderate RI (30-<60)	0			0			0		
Injection site erythema									
Normal (>=90)	0			2	(1.4)	13 6.7	0		
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Injection site dermatitis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Body temperature conditions									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Pyrexia									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Vascular disorders									
Normal (>=90)	1 (1.4)	1	1.0	7 (5.0)	7	3.6	4 (5.1)	4	3.6
Mild RI (60-<90)	1 (3.8)	1	2.9	4 (6.9)	4	5.0	0		
Moderate RI (30-<60)	0			0			0		
Decreased and nonspecific blood pressure disorders and shock									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			3 (5.2)	3	3.8	0		
Moderate RI (30-<60)	0			0			0		
Orthostatic hypotension									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Hypotension									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Vascular hypertensive disorders									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	3 (3.8)	3	2.7
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Hypertension									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	3 (3.8)	3	2.7
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Normal (>=90)	0			2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Arteriosclerosis									
Normal (>=90)	0			2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Embolism and thrombosis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Venous thrombosis limb												
Normal (>=90)	0				0				0			
Mild RI (60-<90)	1	(3.8)	1	2.9	0				0			
Moderate RI (30-<60)	0				0				0			
Reproductive system and breast disorders												
Normal (>=90)	3	(4.1)	4	4.0	7	(5.0)	7	3.6	0			
Mild RI (60-<90)	0				2	(3.4)	3	3.8	0			
Moderate RI (30-<60)	0				0				0			
Menstrual cycle and uterine bleeding disorders												
Normal (>=90)	0				4	(2.9)	4	2.1	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Dysmenorrhoea												
Normal (>=90)	0				2	(1.4)	2	1.0	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Menstrual disorder												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Menstruation irregular												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Prostatic disorders (excl infections and inflammations)									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Benign prostatic hyperplasia									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Male reproductive tract infections and inflammations									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Prostatitis									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Breast disorders									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Breast calcifications									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Menopause related conditions									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Menopausal symptoms									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Uterine, pelvic and broad ligament disorders									
Normal (>=90)	2 (2.7)	3	3.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Endometrial hyperplasia									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Endometriosis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Uterine haemorrhage									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hepatobiliary disorders									
Normal (>=90)	2 (2.7)	2	2.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			4 (6.9)	4	5.0	0		
Moderate RI (30-<60)	0			0			0		
Gallbladder disorders									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Cholelithiasis									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Gallbladder polyp									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Hyperplastic cholecystopathy									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hepatic and hepatobiliary disorders									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Hepatic cyst									
Normal (>=90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Hepatic function abnormal									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Alcoholic liver disease									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hepatic steatosis									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Renal and urinary disorders									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	4 (5.1)	6	5.5
Mild RI (60-<90)	3 (11.5)	4	11.6	3 (5.2)	3	3.8	1 (4.3)	1	3.1
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Renal disorders (excl nephropathies)									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Azotaemia									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Renal cyst									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Urolithiases									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	3 (3.8)	5	4.5
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Ureterolithiasis									
Normal (>=90)	0			1 (0.7)	1	0.5	2 (2.6)	4	3.6
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Calculus urinary									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	1 (100)	1	70.4	0			0		
Urinary tract signs and symptoms									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	2	5.8	0			0		
Moderate RI (30-<60)	0			0			0		
Hyperuricosuria									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Nocturia									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Proteinuria									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Nephropathies									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Diabetic nephropathy									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Nephropathy toxic									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Psychiatric disorders									
Normal (>=90)	4 (5.5)	4	4.0	4 (2.9)	4	2.1	1 (1.3)	1	0.9
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Sleep disorders and disturbances									
Normal (>=90)	3 (4.1)	3	3.0	2 (1.4)	2	1.0	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Insomnia									
Normal (>=90)	3 (4.1)	3	3.0	2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			2 (3.4)	2	2.5	0		
Moderate RI (30-<60)	0			0			0		
Depressed mood disorders and disturbances									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Depression									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Mood disorders and disturbances NEC									
Normal (>=90)	0			1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Emotional disorder									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Listless									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Adjustment disorders (incl subtypes)									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Adjustment disorder									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Cardiac disorders									
Normal (>=90)	1 (1.4)	1	1.0	3 (2.1)	3	1.5	3 (3.8)	3	2.7
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Coronary artery disorders									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Acute myocardial infarction									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Cardiac arrhythmias									
Normal (>=90)	0			2 (1.4)	2	1.0	2 (2.6)	2	1.8
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tachycardia									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Ventricular extrasystoles									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Arrhythmia									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Atrial fibrillation									
Normal (>=90)	0			0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Cardiac disorders, signs and symptoms NEC									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Palpitations									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ear and labyrinth disorders									
Normal (>=90)	3 (4.1)	3	3.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Inner ear and VIIIth cranial nerve disorders									
Normal (>=90)	3 (4.1)	3	3.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Vertigo									
Normal (>=90)	2 (2.7)	2	2.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Tinnitus									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Hearing disorders									
Normal (>=90)	0			2 (1.4)	2	1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Deafness									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Deafness neurosensory									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Normal (>=90)	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
Mild RI (60-<90)	1 (3.8)	1	2.9	1 (1.7)	1	1.3	1 (4.3)	1	3.1
Moderate RI (30-<60)	0			0			0		
Gastrointestinal neoplasms benign									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Intraductal papillary mucinous neoplasm									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Reproductive neoplasms female benign									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Uterine leiomyoma									
Normal (>=90)	0			1 (0.7)	1	0.5	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hepatobiliary neoplasms malignant and unspecified									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(3.8)	1 2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Bile duct adenocarcinoma									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	1	(3.8)	1 2.9	0			0		
Moderate RI (30-<60)	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Clear cell renal cell carcinoma									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(4.3)	1 3.1
Moderate RI (30-<60)	0			0			0		
Lung neoplasm malignant									
Normal (>=90)	0			0			0		
Mild RI (60-<90)	0			0			1	(4.3)	1 3.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Moderate RI (30-<60)	0			0			0		
Immune system disorders									
Normal (>=90)	2 (2.7)	2	2.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Allergic conditions									
Normal (>=90)	2 (2.7)	2	2.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Seasonal allergy									
Normal (>=90)	1 (1.4)	1	1.0	0			1 (1.3)	1	0.9
Mild RI (60-<90)	0			1 (1.7)	1	1.3	0		
Moderate RI (30-<60)	0			0			0		
Food allergy									
Normal (>=90)	1 (1.4)	1	1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Blood and lymphatic system disorders									
Normal (>=90)	2 (2.7)	2	2.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Anaemias nonhaemolytic and marrow depression									
Normal (>=90)	1 (1.4)	1	1.0	2 (1.4)	2	1.0	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Iron deficiency anaemia									
Normal (>=90)	1	(1.4)	1 1.0	2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Anaemia									
Normal (>=90)	0			0			1	(1.3)	1 0.9
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Lymphadenitis									
Normal (>=90)	1	(1.4)	1 1.0	0			0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Congenital, familial and genetic disorders									
Normal (>=90)	0			2	(1.4)	2 1.0	0		
Mild RI (60-<90)	0			0			0		
Moderate RI (30-<60)	0			0			0		
Gastrointestinal tract disorders congenital									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Diverticulitis Meckel's												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Skin and subcutaneous tissue disorders congenital												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Birth mark												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Endocrine disorders												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Thyroid gland disorders												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Hyperthyroidism												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by renal function at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Surgical and medical procedures												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Gastrointestinal therapeutic procedures												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			
Large intestinal polypectomy												
Normal (>=90)	0				1	(0.7)	1	0.5	0			
Mild RI (60-<90)	0				0				0			
Moderate RI (30-<60)	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
RI: Renal impairment
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

31 Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE	
Yes	499		668.3		226		294.9	
No	807		1037.8		429		534.7	
Subjects with events	N	(%)	E	R	N	(%)	E	R
Events								
Yes	450	(90.2)	3509	525.0	193	(85.4)	1124	381.2
No	721	(89.3)	6149	592.5	373	(86.9)	2178	407.3
Serious								
Yes								
Yes	59	(11.8)	71	10.6	17	(7.5)	21	7.1
No	69	(8.6)	93	9.0	25	(5.8)	32	6.0
No								
Yes	449	(90.0)	3438	514.4	190	(84.1)	1103	374.1
No	720	(89.2)	6056	583.6	370	(86.2)	2146	401.3
Severity								
Severe								
Yes	50	(10.0)	92	13.8	15	(6.6)	22	7.5
No	93	(11.5)	150	14.5	29	(6.8)	46	8.6
Moderate								
Yes	269	(53.9)	968	144.8	109	(48.2)	342	116.0
No	454	(56.3)	1644	158.4	202	(47.1)	521	97.4
Mild								
Yes	403	(80.8)	2449	366.4	169	(74.8)	760	257.7
No	676	(83.8)	4355	419.6	338	(78.8)	1611	301.3

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Relationship to trial product								
Missing								
Yes	8	(1.6)	8	1.2	3	(1.3)	4	1.4
No	16	(2.0)	22	2.1	4	(0.9)	4	0.7
Probable								
Yes	198	(39.7)	634	94.9	37	(16.4)	88	29.8
No	373	(46.2)	1514	145.9	110	(25.6)	242	45.3
Possible								
Yes	263	(52.7)	1042	155.9	72	(31.9)	180	61.0
No	463	(57.4)	1658	159.8	151	(35.2)	375	70.1
Unlikely								
Yes	408	(81.8)	1825	273.1	184	(81.4)	852	288.9
No	624	(77.3)	2955	284.7	352	(82.1)	1557	291.2
Outcome								
Fatal								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Recovered								
Yes	438	(87.8)	3003	449.3	188	(83.2)	896	303.9
No	702	(87.0)	5436	523.8	357	(83.2)	1814	339.3
Recovering								
Yes	28	(5.6)	42	6.3	12	(5.3)	17	5.8
No	31	(3.8)	49	4.7	13	(3.0)	20	3.7
Recovered With Sequelae								
Yes	7	(1.4)	15	2.2	2	(0.9)	3	1.0
No	4	(0.5)	4	0.4	2	(0.5)	2	0.4
Not Recovered								
Yes	200	(40.1)	449	67.2	98	(43.4)	207	70.2

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Outcome								
Not Recovered								
No	313	(38.8)	657	63.3	167	(38.9)	341	63.8
Unknown								
Yes	0				1	(0.4)	1	0.3
No	2	(0.2)	3	0.3	0			
Leading to								
Permanent treatment discontinuation								
Yes	34	(6.8)	42	6.3	6	(2.7)	6	2.0
No	58	(7.2)	81	7.8	14	(3.3)	17	3.2
Temporary interruption of trial product								
Yes	47	(9.4)	101	15.1	9	(4.0)	12	4.1
No	79	(9.8)	164	15.8	17	(4.0)	32	6.0
Dose reduction of trial product								
Yes	52	(10.4)	93	13.9	3	(1.3)	8	2.7
No	72	(8.9)	132	12.7	1	(0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

32 Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE	
Yes	499		668.3		226		294.9	
No	807		1037.8		429		534.7	
Subjects with events	N	(%)	E	R	N	(%)	E	R
Adverse events								
Yes	450	(90.2)	3509	525.0	193	(85.4)	1124	381.2
No	721	(89.3)	6149	592.5	373	(86.9)	2178	407.3
Gastrointestinal disorders								
Yes	349	(69.9)	1466	219.4	102	(45.1)	232	78.7
No	620	(76.8)	2843	274.0	212	(49.4)	507	94.8
Gastrointestinal signs and symptoms								
Yes	289	(57.9)	892	133.5	65	(28.8)	124	42.1
No	535	(66.3)	1822	175.6	136	(31.7)	271	50.7
Nausea								
Yes	186	(37.3)	380	56.9	31	(13.7)	42	14.2
No	391	(48.5)	688	66.3	83	(19.3)	104	19.5
Vomiting								
Yes	90	(18.0)	161	24.1	12	(5.3)	15	5.1
No	234	(29.0)	475	45.8	31	(7.2)	37	6.9
Dyspepsia								
Yes	51	(10.2)	68	10.2	8	(3.5)	10	3.4
No	84	(10.4)	111	10.7	15	(3.5)	20	3.7
Abdominal pain								
Yes	42	(8.4)	58	8.7	10	(4.4)	12	4.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	88 (10.9)	117	11.3	26 (6.1)	29	5.4
Abdominal pain upper						
Yes	33 (6.6)	56	8.4	14 (6.2)	15	5.1
No	92 (11.4)	120	11.6	21 (4.9)	22	4.1
Eructation						
Yes	39 (7.8)	46	6.9	2 (0.9)	2	0.7
No	73 (9.0)	93	9.0	1 (0.2)	1	0.2
Abdominal distension						
Yes	29 (5.8)	35	5.2	8 (3.5)	11	3.7
No	67 (8.3)	100	9.6	23 (5.4)	31	5.8
Flatulence						
Yes	26 (5.2)	31	4.6	9 (4.0)	9	3.1
No	39 (4.8)	53	5.1	12 (2.8)	13	2.4
Abdominal discomfort						
Yes	30 (6.0)	39	5.8	1 (0.4)	1	0.3
No	26 (3.2)	40	3.9	8 (1.9)	8	1.5
Abdominal pain lower						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	8 (1.0)	8	0.8	3 (0.7)	3	0.6
Regurgitation						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	2	0.2	0		
Epigastric discomfort						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Faeces soft						
Yes	1 (0.2)	2	0.3	3 (1.3)	3	1.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Gastrointestinal pain						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	3	0.3	0		
Faeces discoloured						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Dysphagia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Retching						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Breath odour						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	3	0.3	0		
Gastrointestinal sounds abnormal						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Abdominal tenderness						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Abnormal faeces						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Faeces hard						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	0				0			
Oesophageal pain								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Aerophagia								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Gastrointestinal motility and defaecation conditions								
Yes	217	(43.5)	447	66.9	49	(21.7)	69	23.4
No	409	(50.7)	824	79.4	117	(27.3)	170	31.8
Diarrhoea								
Yes	129	(25.9)	251	37.6	30	(13.3)	39	13.2
No	283	(35.1)	515	49.6	74	(17.2)	99	18.5
Constipation								
Yes	114	(22.8)	142	21.2	16	(7.1)	18	6.1
No	192	(23.8)	248	23.9	46	(10.7)	55	10.3
Gastrooesophageal reflux disease								
Yes	37	(7.4)	41	6.1	9	(4.0)	9	3.1
No	45	(5.6)	51	4.9	11	(2.6)	12	2.2
Irritable bowel syndrome								
Yes	3	(0.6)	4	0.6	0			
No	3	(0.4)	3	0.3	1	(0.2)	2	0.4
Frequent bowel movements								
Yes	2	(0.4)	2	0.3	1	(0.4)	1	0.3
No	3	(0.4)	3	0.3	2	(0.5)	2	0.4
Dyschezia								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Impaired gastric emptying						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Bowel movement irregularity						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Change of bowel habit						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Defaecation urgency						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Gastrointestinal hypermotility						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Infrequent bowel movements						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Gastrointestinal motility disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Oesophageal achalasia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions						
Yes	26 (5.2)	31	4.6	7 (3.1)	7	2.4
No	45 (5.6)	63	6.1	5 (1.2)	6	1.1
Gastritis						
Yes	17 (3.4)	19	2.8	3 (1.3)	3	1.0
No	33 (4.1)	48	4.6	3 (0.7)	4	0.7
Colitis						
Yes	2 (0.4)	4	0.6	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	0		
Reflux gastritis						
Yes	0			0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Duodenitis						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Chronic gastritis						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Enteritis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal inflammation						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Oesophagitis						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Crohn's disease						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Gastroenteritis eosinophilic						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Colitis ischaemic						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Eosinophilic oesophagitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Epiploic appendagitis						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Inflammatory bowel disease						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Gastrointestinal conditions NEC						
Yes	16	(3.2)	25 3.7	2	(0.9)	2 0.7
No	32	(4.0)	42 4.0	10	(2.3)	14 2.6
Hyperchlorhydria						
Yes	7	(1.4)	15 2.2	0		
No	13	(1.6)	22 2.1	3	(0.7)	5 0.9
Food poisoning						
Yes	4	(0.8)	4 0.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	14 (1.7)	14	1.3	4 (0.9)	6	1.1
Gastrointestinal disorder						
Yes	2 (0.4)	3	0.4	1 (0.4)	1	0.3
No	3 (0.4)	4	0.4	3 (0.7)	3	0.6
Anal fistula						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Functional gastrointestinal disorder						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Gastric mucosal hypertrophy						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Barrett's oesophagus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal vascular conditions						
Yes	11 (2.2)	12	1.8	1 (0.4)	1	0.3
No	17 (2.1)	18	1.7	4 (0.9)	4	0.7
Haemorrhoids						
Yes	10 (2.0)	10	1.5	0		
No	16 (2.0)	17	1.6	3 (0.7)	3	0.6
Haemorrhoidal haemorrhage						
Yes	1 (0.2)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Haemorrhoids thrombosed						
Yes	0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	1	(0.1)	1	<0.1	0			
Dental and gingival conditions								
Yes	9	(1.8)	11	1.6	12	(5.3)	13	4.4
No	18	(2.2)	21	2.0	17	(4.0)	19	3.6
Toothache								
Yes	4	(0.8)	5	0.7	3	(1.3)	3	1.0
No	13	(1.6)	15	1.4	14	(3.3)	15	2.8
Dental caries								
Yes	3	(0.6)	4	0.6	7	(3.1)	7	2.4
No	1	(0.1)	1	<0.1	3	(0.7)	3	0.6
Noninfective gingivitis								
Yes	1	(0.2)	1	0.1	1	(0.4)	1	0.3
No	0				0			
Periodontal disease								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Gingival bleeding								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Gingival disorder								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Gingival pain								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Tooth impacted								
Yes	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Tooth loss						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Dental necrosis						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Dental pulp disorder						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Tooth disorder						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Salivary gland conditions						
Yes	8	(1.6)	8 1.2	4	(1.8)	4 1.4
No	19	(2.4)	19 1.8	4	(0.9)	5 0.9
Dry mouth						
Yes	8	(1.6)	8 1.2	3	(1.3)	3 1.0
No	17	(2.1)	17 1.6	4	(0.9)	5 0.9
Salivary gland calculus						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Salivary gland cyst						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Salivary gland enlargement						
Yes	0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Gastrointestinal haemorrhages NEC						
Yes	6 (1.2)	6	0.9	3 (1.3)	3	1.0
No	9 (1.1)	10	1.0	3 (0.7)	4	0.7
Rectal haemorrhage						
Yes	3 (0.6)	3	0.4	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Haematochezia						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	2 (0.5)	3	0.6
Lower gastrointestinal haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Haematemesis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Melaena						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Upper gastrointestinal haemorrhage						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Benign neoplasms gastrointestinal						
Yes	7 (1.4)	7	1.0	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	4 (0.9)	4	0.7
Large intestine polyp						
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Gastric polyps						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Abdominal hernias and other abdominal wall conditions						
Yes	5 (1.0)	5	0.7	3 (1.3)	3	1.0
No	4 (0.5)	5	0.5	1 (0.2)	1	0.2
Hiatus hernia						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	3 (0.4)	4	0.4	0		
Abdominal hernia						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Umbilical hernia						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Oral soft tissue conditions						
Yes	4 (0.8)	5	0.7	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	5 (1.2)	5	0.9
Lip swelling						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Cheilitis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Mouth ulceration						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			2 (0.5)	2	0.4
Paraesthesia oral						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Stomatitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Aphthous ulcer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lip disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Odynophagia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Oral mucosal eruption						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Diverticular disorders						
Yes	5 (1.0)	5	0.7	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Diverticulum						
Yes	5 (1.0)	5	0.7	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Anal and rectal conditions NEC						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	3 (0.6)	4	0.6	0		
No	4 (0.5)	5	0.5	0		
Anal fissure						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Proctalgia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	2	0.2	0		
Anorectal discomfort						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Anal pruritus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Rectal fissure						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal ulceration and perforation						
Yes	4 (0.8)	4	0.6	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Gastric ulcer						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Large intestine perforation						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Oesophageal ulcer						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Peptic ulcer						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Duodenal ulcer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal stenosis and obstruction						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Ileus						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Volvulus						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Oesophageal stenosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Intestinal obstruction						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Exocrine pancreas conditions						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	2	(0.2)	2	0.2	0			
Pancreatitis acute								
Yes	0				0			
No	2	(0.2)	2	0.2	0			
Peritoneal and retroperitoneal conditions								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Pneumoperitoneum								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Tongue conditions								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Glossodynia								
Yes	1	(0.2)	1	0.1	0			
No	0				0			
Malabsorption conditions								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Coeliac disease								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Infections and infestations								
Yes	281	(56.3)	562	84.1	127	(56.2)	261	88.5
No	433	(53.7)	1053	101.5	245	(57.1)	541	101.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Infections - pathogen unspecified						
Yes	242 (48.5)	436	65.2	101 (44.7)	190	64.4
No	384 (47.6)	811	78.1	213 (49.7)	420	78.5
Nasopharyngitis						
Yes	96 (19.2)	154	23.0	42 (18.6)	65	22.0
No	185 (22.9)	326	31.4	91 (21.2)	151	28.2
Upper respiratory tract infection						
Yes	47 (9.4)	63	9.4	21 (9.3)	28	9.5
No	67 (8.3)	95	9.2	59 (13.8)	88	16.5
Gastroenteritis						
Yes	36 (7.2)	40	6.0	13 (5.8)	16	5.4
No	49 (6.1)	64	6.2	17 (4.0)	22	4.1
Sinusitis						
Yes	22 (4.4)	26	3.9	12 (5.3)	14	4.7
No	49 (6.1)	58	5.6	24 (5.6)	26	4.9
Urinary tract infection						
Yes	25 (5.0)	29	4.3	4 (1.8)	7	2.4
No	43 (5.3)	54	5.2	24 (5.6)	27	5.0
Bronchitis						
Yes	21 (4.2)	24	3.6	10 (4.4)	12	4.1
No	26 (3.2)	28	2.7	15 (3.5)	16	3.0
Cystitis						
Yes	7 (1.4)	7	1.0	1 (0.4)	1	0.3
No	12 (1.5)	14	1.3	2 (0.5)	2	0.4
Rhinitis						
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3
No	13 (1.6)	19	1.8	8 (1.9)	13	2.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pharyngitis						
Yes	4 (0.8)	4	0.6	5 (2.2)	5	1.7
No	9 (1.1)	9	0.9	4 (0.9)	4	0.7
Laryngitis						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	12 (1.5)	12	1.2	3 (0.7)	3	0.6
Tonsillitis						
Yes	5 (1.0)	7	1.0	4 (1.8)	5	1.7
No	7 (0.9)	8	0.8	6 (1.4)	7	1.3
Acute sinusitis						
Yes	6 (1.2)	6	0.9	4 (1.8)	5	1.7
No	5 (0.6)	6	0.6	4 (0.9)	4	0.7
Pneumonia						
Yes	5 (1.0)	6	0.9	5 (2.2)	5	1.7
No	6 (0.7)	8	0.8	3 (0.7)	3	0.6
Tooth infection						
Yes	5 (1.0)	6	0.9	0		
No	6 (0.7)	6	0.6	5 (1.2)	5	0.9
Vaginal infection						
Yes	2 (0.4)	2	0.3	0		
No	9 (1.1)	11	1.1	0		
Ear infection						
Yes	4 (0.8)	5	0.7	0		
No	5 (0.6)	6	0.6	3 (0.7)	3	0.6
Lower respiratory tract infection						
Yes	2 (0.4)	3	0.4	1 (0.4)	4	1.4
No	7 (0.9)	7	0.7	11 (2.6)	12	2.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tooth abscess						
Yes	1 (0.2)	1	0.1	6 (2.7)	6	2.0
No	7 (0.9)	7	0.7	2 (0.5)	3	0.6
Conjunctivitis						
Yes	2 (0.4)	2	0.3	0		
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Otitis media						
Yes	1 (0.2)	1	0.1	0		
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Appendicitis						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Eye infection						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	0		
Gastrointestinal infection						
Yes	2 (0.4)	3	0.4	3 (1.3)	3	1.0
No	3 (0.4)	4	0.4	0		
Pulpitis dental						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	0		
Folliculitis						
Yes	1 (0.2)	1	0.1	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Chronic sinusitis						
Yes	3 (0.6)	3	0.4	1 (0.4)	1	0.3
No	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast abscess						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Gingivitis						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Hordeolum						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Pharyngotonsillitis						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	2	0.4
Pyelonephritis						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Infected bite						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Kidney infection						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Subcutaneous abscess						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Abdominal wall abscess						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abscess						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Atypical pneumonia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Diarrhoea infectious						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Infection						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Omphalitis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Postoperative wound infection						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Localised infection						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Otitis externa						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Periodontitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abdominal abscess						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Abscess limb						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Device related infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Diverticulitis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Eyelid infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Haematoma infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Large intestine infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Oophoritis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Osteomyelitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Parasitic gastroenteritis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Paronychia						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Perirectal abscess						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Peritonitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Prostate infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Salpingitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Sepsis syndrome						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Appendicitis perforated						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Bartholinitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Carbuncle						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Endometritis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Epididymitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Fracture infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Groin abscess						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Mastitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Nail infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Oral infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Parotitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Purulence						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Respiratory tract infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Skin infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Arthritis infective						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Cervicitis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Empyema						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Gastric infection						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Infected dermal cyst						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Lymphangitis						
Yes	0			1	(0.4)	1 0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Neutropenic sepsis								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Otitis media acute								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Peritonsillar abscess								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Peritonsillitis								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Root canal infection								
Yes	0				1	(0.4)	1	0.3
No	0				1	(0.2)	1	0.2
Septic shock								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Tracheitis								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Wound infection								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Viral infectious disorders								
Yes	64	(12.8)	79	11.8	39	(17.3)	46	15.6
No	130	(16.1)	169	16.3	64	(14.9)	90	16.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Influenza						
Yes	25 (5.0)	34	5.1	22 (9.7)	26	8.8
No	64 (7.9)	78	7.5	41 (9.6)	53	9.9
Gastroenteritis viral						
Yes	11 (2.2)	11	1.6	5 (2.2)	5	1.7
No	31 (3.8)	33	3.2	9 (2.1)	10	1.9
Viral infection						
Yes	7 (1.4)	10	1.5	3 (1.3)	3	1.0
No	7 (0.9)	10	1.0	5 (1.2)	5	0.9
Herpes zoster						
Yes	3 (0.6)	3	0.4	4 (1.8)	4	1.4
No	9 (1.1)	10	1.0	7 (1.6)	7	1.3
Gastrointestinal viral infection						
Yes	7 (1.4)	8	1.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Viral upper respiratory tract infection						
Yes	2 (0.4)	2	0.3	0		
No	5 (0.6)	5	0.5	4 (0.9)	5	0.9
Herpes simplex						
Yes	3 (0.6)	3	0.4	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Oral herpes						
Yes	3 (0.6)	3	0.4	0		
No	1 (0.1)	2	0.2	1 (0.2)	1	0.2
Gastroenteritis norovirus						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	4 (0.5)	5	0.5	0		
Ear infection viral						
Yes	0			0		
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Viral pharyngitis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Dengue fever						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Herpes virus infection						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Respiratory tract infection viral						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Gastroenteritis astroviral						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Chronic hepatitis B						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cytomegalovirus infection						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Genital herpes zoster						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	1	(0.1)	1	<0.1	0			
Hepatitis E								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Infectious mononucleosis								
Yes	0				0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Oral viral infection								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Papilloma viral infection								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Parainfluenzae virus infection								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Respiratory syncytial virus infection								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Varicella								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Vestibular neuronitis								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Viral sinusitis								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Bronchitis viral						
Yes	0			2 (0.9)	2	0.7
No	0			0		
Conjunctivitis viral						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hand-foot-and-mouth disease						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Meningitis viral						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Viral rhinitis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bacterial infectious disorders						
Yes	28 (5.6)	30	4.5	13 (5.8)	15	5.1
No	29 (3.6)	33	3.2	14 (3.3)	16	3.0
Pharyngitis streptococcal						
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	5 (1.2)	5	0.9
Cellulitis						
Yes	7 (1.4)	7	1.0	4 (1.8)	4	1.4
No	2 (0.2)	2	0.2	3 (0.7)	4	0.7
Ear infection bacterial						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Helicobacter infection						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Bacterial vaginosis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	4 (0.5)	7	0.7	1 (0.2)	1	0.2
Erysipelas						
Yes	3 (0.6)	3	0.4	0		
No	0			0		
Furuncle						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	3	0.3	0		
Staphylococcal infection						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Helicobacter gastritis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Bacterial vulvovaginitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Lyme disease						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Pharyngitis bacterial						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Salmonellosis						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Sinusitis bacterial						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Bacterial colitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Genital infection bacterial						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Skin bacterial infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Syphilis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Tonsillitis bacterial						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Typhoid fever						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Bacteriuria						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Gastric ulcer helicobacter						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Listeriosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Staphylococcal sepsis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Streptococcal urinary tract infection						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Upper respiratory tract infection bacterial						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Fungal infectious disorders						
Yes	15 (3.0)	16	2.4	8 (3.5)	9	3.1
No	30 (3.7)	37	3.6	14 (3.3)	15	2.8
Vulvovaginal mycotic infection						
Yes	3 (0.6)	4	0.6	1 (0.4)	1	0.3
No	8 (1.0)	9	0.9	1 (0.2)	1	0.2
Fungal infection						
Yes	2 (0.4)	2	0.3	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	8 (1.0)	9	0.9	5 (1.2)	5	0.9
Tinea pedis						
Yes	1 (0.2)	1	0.1	0		
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Vulvovaginal candidiasis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	4 (0.5)	7	0.7	2 (0.5)	2	0.4
Fungal skin infection						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Body tinea						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Dermatophytosis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Onychomycosis						
Yes	1 (0.2)	1	0.1	3 (1.3)	4	1.4
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Skin candida						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Tinea capitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Tinea cruris						
Yes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Candida infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	2	(0.5)	2 0.4
Dermatophytosis of nail						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Tinea infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Oral candidiasis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Otitis externa fungal						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Protozoal infectious disorders						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Trichomoniasis						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Toxoplasmosis						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Chlamydial infectious disorders						
Yes	1	(0.2)	1 0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Chlamydial infection						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Ectoparasitic disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Acarodermatitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nervous system disorders						
Yes	153 (30.7)	302	45.2	46 (20.4)	72	24.4
No	238 (29.5)	456	43.9	95 (22.1)	150	28.1
Headaches						
Yes	85 (17.0)	174	26.0	26 (11.5)	32	10.9
No	144 (17.8)	277	26.7	63 (14.7)	86	16.1
Headache						
Yes	72 (14.4)	157	23.5	23 (10.2)	28	9.5
No	126 (15.6)	230	22.2	57 (13.3)	76	14.2
Migraine						
Yes	9 (1.8)	12	1.8	3 (1.3)	3	1.0
No	23 (2.9)	40	3.9	6 (1.4)	8	1.5
Sinus headache						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	0		
Tension headache						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Migraine with aura						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Occipital neuralgia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Neurological disorders NEC						
Yes	74 (14.8)	97	14.5	18 (8.0)	28	9.5
No	107 (13.3)	151	14.6	29 (6.8)	40	7.5
Dizziness						
Yes	38 (7.6)	44	6.6	7 (3.1)	10	3.4
No	60 (7.4)	86	8.3	16 (3.7)	25	4.7
Dysgeusia						
Yes	6 (1.2)	8	1.2	4 (1.8)	11	3.7
No	12 (1.5)	16	1.5	0		
Paraesthesia						
Yes	7 (1.4)	9	1.3	1 (0.4)	1	0.3
No	6 (0.7)	8	0.8	4 (0.9)	4	0.7
Syncope						
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Hypoaesthesia						
Yes	6 (1.2)	6	0.9	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Taste disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	2 (0.4)	3	0.4	1 (0.4)	1	0.3
No	7 (0.9)	8	0.8	0		
Lethargy						
Yes	3 (0.6)	3	0.4	0		
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Somnolence						
Yes	2 (0.4)	3	0.4	1 (0.4)	1	0.3
No	5 (0.6)	6	0.6	0		
Hyperaesthesia						
Yes	2 (0.4)	4	0.6	0		
No	2 (0.2)	2	0.2	0		
Neuralgia						
Yes	0			1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Dizziness postural						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Allodynia						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Presyncope						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Balance disorder						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Burning sensation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Ageusia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Aphasia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Dysarthria						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Loss of consciousness						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Vertigo CNS origin						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Dysaesthesia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Hyporeflexia						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Restless legs syndrome						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	2 0.2	1	(0.2)	1 0.2
Sensory disturbance						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sensory loss						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Spinal cord and nerve root disorders						
Yes	10 (2.0)	10	1.5	6 (2.7)	6	2.0
No	10 (1.2)	12	1.2	8 (1.9)	8	1.5
Sciatica						
Yes	6 (1.2)	6	0.9	4 (1.8)	4	1.4
No	8 (1.0)	10	1.0	4 (0.9)	4	0.7
Cervicobrachial syndrome						
Yes	2 (0.4)	2	0.3	0		
No	0			4 (0.9)	4	0.7
Cervical radiculopathy						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Spinal cord compression						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Lumbar radiculopathy						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lumbosacral radiculopathy						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Peripheral neuropathies						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	8 (1.6)	9	1.3	2 (0.9)	2	0.7
No	4 (0.5)	4	0.4	6 (1.4)	7	1.3
Neuropathy peripheral						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Carpal tunnel syndrome						
Yes	3 (0.6)	4	0.6	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Nerve compression						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Peripheral sensory neuropathy						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Peroneal nerve palsy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Radial nerve compression						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Movement disorders (incl parkinsonism)						
Yes	4 (0.8)	4	0.6	1 (0.4)	2	0.7
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Tremor						
Yes	3 (0.6)	3	0.4	1 (0.4)	2	0.7
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Essential tremor						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Mental impairment disorders						
Yes	3 (0.6)	3	0.4	0		
No	2 (0.2)	2	0.2	3 (0.7)	4	0.7
Memory impairment						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Amnesia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Disturbance in attention						
Yes	1 (0.2)	1	0.1	0		
No	0			3 (0.7)	4	0.7
Dementia Alzheimer's type						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cranial nerve disorders (excl neoplasms)						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	0		
Anosmia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Parosmia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cranial nerve disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Sleep disturbances (incl subtypes)						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Poor quality sleep						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Central nervous system vascular disorders						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Cerebral infarction						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Ischaemic stroke						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Neuromuscular disorders						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Autonomic nervous system imbalance						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Increased intracranial pressure and hydrocephalus						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	1	(0.1)	2 0.2	0		
Idiopathic intracranial hypertension						
Yes	0			0		
No	1	(0.1)	2 0.2	0		
Neurological disorders of the eye						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Visual field defect						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Demyelinating disorders						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Multiple sclerosis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Seizures (incl subtypes)						
Yes	0			1	(0.4)	1 0.3
No	0			1	(0.2)	1 0.2
Partial seizures						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Psychogenic seizure						
Yes	0			1	(0.4)	1 0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue disorders						
Yes	132 (26.5)	233	34.9	76 (33.6)	125	42.4
No	206 (25.5)	325	31.3	110 (25.6)	179	33.5
Musculoskeletal and connective tissue disorders NEC						
Yes	72 (14.4)	92	13.8	37 (16.4)	54	18.3
No	115 (14.3)	152	14.6	62 (14.5)	78	14.6
Back pain						
Yes	41 (8.2)	48	7.2	19 (8.4)	20	6.8
No	66 (8.2)	73	7.0	35 (8.2)	36	6.7
Pain in extremity						
Yes	20 (4.0)	20	3.0	11 (4.9)	13	4.4
No	24 (3.0)	28	2.7	13 (3.0)	15	2.8
Musculoskeletal pain						
Yes	11 (2.2)	11	1.6	7 (3.1)	9	3.1
No	20 (2.5)	20	1.9	9 (2.1)	9	1.7
Neck pain						
Yes	6 (1.2)	6	0.9	3 (1.3)	3	1.0
No	13 (1.6)	15	1.4	6 (1.4)	6	1.1
Musculoskeletal chest pain						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Musculoskeletal stiffness						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Flank pain						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Plantar fasciitis						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	4 (0.9)	5	0.9
Axillary mass						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Dupuytren's contracture						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Musculoskeletal discomfort						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Groin pain						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Limb mass						
Yes	0			1 (0.4)	2	0.7
No	0			0		
Muscle contracture						
Yes	0			2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Neck mass						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Joint disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	54 (10.8)	72	10.8	30 (13.3)	35	11.9
No	79 (9.8)	97	9.3	45 (10.5)	59	11.0
Arthralgia						
Yes	32 (6.4)	37	5.5	14 (6.2)	15	5.1
No	49 (6.1)	55	5.3	29 (6.8)	32	6.0
Osteoarthritis						
Yes	12 (2.4)	16	2.4	8 (3.5)	9	3.1
No	11 (1.4)	12	1.2	10 (2.3)	11	2.1
Spinal osteoarthritis						
Yes	4 (0.8)	4	0.6	0		
No	8 (1.0)	9	0.9	0		
Arthritis						
Yes	5 (1.0)	5	0.7	3 (1.3)	3	1.0
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Rotator cuff syndrome						
Yes	4 (0.8)	4	0.6	0		
No	2 (0.2)	2	0.2	5 (1.2)	5	0.9
Joint swelling						
Yes	0			2 (0.9)	2	0.7
No	7 (0.9)	7	0.7	2 (0.5)	2	0.4
Joint stiffness						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Vertebral foraminal stenosis						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	2	0.2	0		
Facet joint syndrome						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	2 0.2	0		
Periarthritis						
Yes	1	(0.2)	1 0.1	0		
No	0			1	(0.2)	2 0.4
Arthropathy						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	2 0.2	0		
Spondylitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Vertebral osteophyte						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Chondromalacia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Haemarthrosis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Joint noise						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Joint range of motion decreased						
Yes	0			2	(0.9)	2 0.7
No	0			0		
Joint space narrowing						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Polyarthritis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Rheumatoid arthritis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Spondyloarthropathy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Muscle disorders						
Yes	25 (5.0)	31	4.6	9 (4.0)	9	3.1
No	33 (4.1)	33	3.2	14 (3.3)	20	3.7
Myalgia						
Yes	12 (2.4)	15	2.2	3 (1.3)	3	1.0
No	11 (1.4)	11	1.1	5 (1.2)	10	1.9
Muscle spasms						
Yes	6 (1.2)	6	0.9	3 (1.3)	3	1.0
No	13 (1.6)	13	1.3	7 (1.6)	8	1.5
Muscular weakness						
Yes	4 (0.8)	5	0.7	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Fibromyalgia						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Myofascial pain syndrome						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Muscle fatigue						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Muscle twitching						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Torticollis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Muscle disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Muscle tightness						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Myalgia intercostal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Myosclerosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tendon, ligament and cartilage disorders						
Yes	9 (1.8)	9	1.3	8 (3.5)	9	3.1
No	16 (2.0)	18	1.7	5 (1.2)	6	1.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tendonitis						
Yes	5 (1.0)	5	0.7	4 (1.8)	5	1.7
No	8 (1.0)	9	0.9	5 (1.2)	6	1.1
Costochondritis						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Tenosynovitis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Tendon disorder						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Trigger finger						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	0			0		
Osteochondrosis						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Posterior tibial tendon dysfunction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tendon discomfort						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tendon pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)						
Yes	7 (1.4)	11	1.6	5 (2.2)	6	2.0
No	12 (1.5)	13	1.3	6 (1.4)	7	1.3
Intervertebral disc protrusion						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	2 (0.5)	3	0.6
Intervertebral disc degeneration						
Yes	2 (0.4)	4	0.6	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Scoliosis						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Cervical spinal stenosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Finger deformity						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Intervertebral disc displacement						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Kyphoscoliosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Spinal stenosis						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Spondylolisthesis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Foot deformity						
Yes	0			1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Intervertebral disc annular tear						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Kyphosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Synovial and bursal disorders						
Yes	10 (2.0)	10	1.5	3 (1.3)	3	1.0
No	6 (0.7)	6	0.6	2 (0.5)	2	0.4
Bursitis						
Yes	5 (1.0)	5	0.7	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Synovial cyst						
Yes	4 (0.8)	4	0.6	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Synovitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Bursal fluid accumulation						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bone disorders (excl congenital and fractures)						
Yes	6 (1.2)	7	1.0	7 (3.1)	7	2.4
No	5 (0.6)	5	0.5	7 (1.6)	7	1.3
Osteopenia						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Pain in jaw						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Bone cyst						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Exostosis						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Osteonecrosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Osteoporosis						
Yes	1 (0.2)	1	0.1	3 (1.3)	3	1.0
No	0			0		
Coccydynia						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Metatarsalgia						
Yes	0			2	(0.9)	2 0.7
No	1	(0.1)	1 <0.1	0		
Pubic pain						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Connective tissue disorders (excl congenital)						
Yes	1	(0.2)	1 0.1	2	(0.9)	2 0.7
No	1	(0.1)	1 <0.1	0		
Myofascitis						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Sjogren's syndrome						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Systemic lupus erythematosus						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Systemic scleroderma						
Yes	0			1	(0.4)	1 0.3
No	0			0		
General disorders and administration site conditions						
Yes	108	(21.6)	169 25.3	29	(12.8)	57 19.3
No	183	(22.7)	296 28.5	102	(23.8)	165 30.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
General system disorders NEC						
Yes	89 (17.8)	130	19.5	23 (10.2)	32	10.9
No	136 (16.9)	194	18.7	63 (14.7)	81	15.1
Fatigue						
Yes	42 (8.4)	53	7.9	7 (3.1)	7	2.4
No	62 (7.7)	67	6.5	21 (4.9)	22	4.1
Asthenia						
Yes	16 (3.2)	20	3.0	3 (1.3)	3	1.0
No	19 (2.4)	33	3.2	8 (1.9)	9	1.7
Early satiety						
Yes	9 (1.8)	9	1.3	1 (0.4)	1	0.3
No	17 (2.1)	17	1.6	1 (0.2)	1	0.2
Pain						
Yes	7 (1.4)	8	1.2	0		
No	14 (1.7)	15	1.4	7 (1.6)	7	1.3
Malaise						
Yes	8 (1.6)	11	1.6	1 (0.4)	1	0.3
No	8 (1.0)	8	0.8	3 (0.7)	4	0.7
Influenza like illness						
Yes	6 (1.2)	6	0.9	2 (0.9)	2	0.7
No	11 (1.4)	12	1.2	11 (2.6)	11	2.1
Chest discomfort						
Yes	4 (0.8)	4	0.6	1 (0.4)	2	0.7
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Chills						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Non-cardiac chest pain						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Hunger						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Oedema peripheral						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	5 (1.2)	5	0.9
Chest pain						
Yes	1 (0.2)	1	0.1	5 (2.2)	5	1.7
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Thirst						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Feeling hot						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Hernia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Ill-defined disorder						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Peripheral swelling						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	4 (0.9)	4	0.7

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Swelling						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Feeling cold						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Sensation of foreign body						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Swelling face						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Axillary pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Crying						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Fat tissue increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hangover						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Inflammation						
Yes	0			0		
No	1 (0.1)	2	0.2	1 (0.2)	1	0.2

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Pseudocyst						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Sense of oppression						
Yes	0			0		
No	1	(0.1)	2 0.2	0		
Sluggishness						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Discomfort						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Facial pain						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Granuloma						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Gravitational oedema						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Temperature intolerance						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Administration site reactions						
Yes	13	(2.6)	26 3.9	11	(4.9)	22 7.5
No	52	(6.4)	73 7.0	33	(7.7)	60 11.2

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Injection site bruising						
Yes	4 (0.8)	5	0.7	8 (3.5)	8	2.7
No	24 (3.0)	26	2.5	18 (4.2)	26	4.9
Injection site pain						
Yes	3 (0.6)	3	0.4	3 (1.3)	3	1.0
No	16 (2.0)	21	2.0	13 (3.0)	18	3.4
Injection site pruritus						
Yes	3 (0.6)	3	0.4	0		
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Injection site mass						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Injection site haematoma						
Yes	2 (0.4)	7	1.0	1 (0.4)	9	3.1
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Injection site reaction						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Injection site erythema						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Injection site haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Application site haematoma						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Injection site inflammation						
Yes	0			0		
No	2 (0.2)	4	0.4	0		
Injection site paraesthesia						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Infusion site extravasation						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Injection site induration						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Injection site urticaria						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Vessel puncture site bruise						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Injection site swelling						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Vessel puncture site rash						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Application site bruise						
Yes	0			0		
No	0			1 (0.2)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Puncture site pain						
Yes	0			0		
No	0			1 (0.2)	2	0.4
Body temperature conditions						
Yes	8 (1.6)	9	1.3	3 (1.3)	3	1.0
No	19 (2.4)	24	2.3	14 (3.3)	18	3.4
Pyrexia						
Yes	8 (1.6)	9	1.3	3 (1.3)	3	1.0
No	19 (2.4)	24	2.3	14 (3.3)	18	3.4
Tissue disorders NEC						
Yes	3 (0.6)	3	0.4	0		
No	2 (0.2)	2	0.2	5 (1.2)	5	0.9
Cyst						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Nodule						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Dysplasia						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Fat necrosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hyperplasia						
Yes	0			0		
No	0			1 (0.2)	1	0.2

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Complications associated with device						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Vascular stent occlusion						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Injury associated with device						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Therapeutic and nontherapeutic effects (excl toxicity)						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Withdrawal syndrome						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Metabolism and nutrition disorders						
Yes	83	(16.6)	118 17.7	30	(13.3)	44 14.9
No	116	(14.4)	149 14.4	53	(12.4)	64 12.0
Appetite and general nutritional disorders						
Yes	59	(11.8)	73 10.9	11	(4.9)	14 4.7
No	82	(10.2)	99 9.5	17	(4.0)	22 4.1
Decreased appetite						
Yes	51	(10.2)	59 8.8	7	(3.1)	8 2.7
No	73	(9.0)	80 7.7	15	(3.5)	18 3.4

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Food craving						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Hyperphagia						
Yes	4 (0.8)	5	0.7	2 (0.9)	4	1.4
No	3 (0.4)	3	0.3	0		
Increased appetite						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	5 (0.6)	6	0.6	1 (0.2)	1	0.2
Food aversion						
Yes	1 (0.2)	3	0.4	0		
No	3 (0.4)	3	0.3	0		
Lack of satiety						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Malnutrition						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Vitamin related disorders						
Yes	10 (2.0)	14	2.1	2 (0.9)	2	0.7
No	12 (1.5)	14	1.3	8 (1.9)	10	1.9
Vitamin D deficiency						
Yes	7 (1.4)	7	1.0	1 (0.4)	1	0.3
No	10 (1.2)	10	1.0	7 (1.6)	7	1.3
Vitamin B12 deficiency						
Yes	4 (0.8)	4	0.6	0		
No	2 (0.2)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Folate deficiency						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Vitamin A deficiency						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Vitamin B2 deficiency						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Vitamin B complex deficiency						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Lipid metabolism disorders						
Yes	11 (2.2)	11	1.6	7 (3.1)	8	2.7
No	9 (1.1)	10	1.0	13 (3.0)	13	2.4
Dyslipidaemia						
Yes	6 (1.2)	6	0.9	4 (1.8)	5	1.7
No	4 (0.5)	4	0.4	5 (1.2)	5	0.9
Hypercholesterolaemia						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	4 (0.9)	4	0.7
Hypertriglyceridaemia						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Cholesterosis						
Yes	0			0		
No	1 (0.1)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hyperlipidaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	4 (0.9)	4	0.7
Electrolyte and fluid balance conditions						
Yes	5 (1.0)	8	1.2	3 (1.3)	3	1.0
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Hypokalaemia						
Yes	2 (0.4)	4	0.6	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Hyponatraemia						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Hyperkalaemia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Dehydration						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Electrolyte imbalance						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Polydipsia						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Fluid retention						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Glucose metabolism disorders (incl diabetes mellitus)						
Yes	2 (0.4)	2	0.3	11 (4.9)	15	5.1
No	8 (1.0)	15	1.4	10 (2.3)	10	1.9
Hypoglycaemia						
Yes	2 (0.4)	2	0.3	2 (0.9)	4	1.4
No	5 (0.6)	11	1.1	3 (0.7)	3	0.6
Glucose tolerance impaired						
Yes	0			3 (1.3)	3	1.0
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Postprandial hypoglycaemia						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Type 2 diabetes mellitus						
Yes	0			4 (1.8)	5	1.7
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Diabetes mellitus						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hyperglycaemia						
Yes	0			0		
No	0			2 (0.5)	2	0.4
Impaired fasting glucose						
Yes	0			2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Insulin resistance						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Purine and pyrimidine metabolism disorders						
Yes	4 (0.8)	5	0.7	1 (0.4)	1	0.3
No	0			3 (0.7)	3	0.6
Gout						
Yes	4 (0.8)	5	0.7	1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Hyperuricaemia						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Iron and trace metal metabolism disorders						
Yes	0			1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Iron deficiency						
Yes	0			1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Food intolerance syndromes						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Dairy intolerance						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Lactose intolerance						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Food intolerance						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Metabolism disorders NEC						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Hyperlipasaemia						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Bone, calcium, magnesium and phosphorus metabolism disorders						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Hypomagnesaemia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Protein and amino acid metabolism disorders NEC						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Hypoalbuminaemia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Injury, poisoning and procedural complications						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	78 (15.6)	109	16.3	49 (21.7)	77	26.1
No	110 (13.6)	155	14.9	72 (16.8)	99	18.5
Injuries NEC						
Yes	48 (9.6)	63	9.4	40 (17.7)	57	19.3
No	78 (9.7)	105	10.1	56 (13.1)	73	13.7
Ligament sprain						
Yes	7 (1.4)	9	1.3	9 (4.0)	10	3.4
No	14 (1.7)	15	1.4	10 (2.3)	10	1.9
Fall						
Yes	10 (2.0)	10	1.5	5 (2.2)	7	2.4
No	9 (1.1)	9	0.9	7 (1.6)	12	2.2
Muscle strain						
Yes	8 (1.6)	8	1.2	8 (3.5)	8	2.7
No	9 (1.1)	10	1.0	7 (1.6)	7	1.3
Contusion						
Yes	4 (0.8)	6	0.9	4 (1.8)	7	2.4
No	11 (1.4)	13	1.3	11 (2.6)	12	2.2
Skin laceration						
Yes	3 (0.6)	3	0.4	4 (1.8)	5	1.7
No	6 (0.7)	6	0.6	4 (0.9)	4	0.7
Arthropod bite						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	7 (0.9)	7	0.7	5 (1.2)	5	0.9
Arthropod sting						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	0		
Skin abrasion						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	3 (0.6)	3	0.4	3 (1.3)	3	1.0
No	2 (0.2)	5	0.5	0		
Limb injury						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Concussion						
Yes	4 (0.8)	4	0.6	0		
No	0			2 (0.5)	2	0.4
Tooth fracture						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Ligament rupture						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Epicondylitis						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Animal bite						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Muscle rupture						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Road traffic accident						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Back injury						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	3	(0.4)	3 0.3	1	(0.2)	1 0.2
Wound						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	2	(0.5)	2 0.4
Injury						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Eyelid injury						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Ligament injury						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Skeletal injury						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Soft tissue foreign body						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Bone contusion						
Yes	0			0		
No	1	(0.1)	1 <0.1	2	(0.5)	2 0.4
Eye burns						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Eyelid contusion						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Face injury								
Yes	0				1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Foreign body in eye								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Head injury								
Yes	0				1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Muscle injury								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Musculoskeletal injury								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Nerve injury								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Post-traumatic neck syndrome								
Yes	0				0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Post-traumatic pain								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Subdural haematoma								

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tendon injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Chest injury						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Corneal abrasion						
Yes	0			0		
No	0			2 (0.5)	2	0.4
Eye injury						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Gun shot wound						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Post concussion syndrome						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Scar						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Tendon rupture						
Yes	0			2 (0.9)	3	1.0
No	0			0		
Bone and joint injuries						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	19 (3.8)	20	3.0	9 (4.0)	10	3.4
No	16 (2.0)	19	1.8	13 (3.0)	13	2.4
Foot fracture						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	2 (0.2)	4	0.4	3 (0.7)	3	0.6
Joint injury						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	0		
Meniscus injury						
Yes	2 (0.4)	2	0.3	2 (0.9)	3	1.0
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Radius fracture						
Yes	3 (0.6)	3	0.4	0		
No	0			1 (0.2)	1	0.2
Joint dislocation						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hand fracture						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Rib fracture						
Yes	0			0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Ankle fracture						
Yes	1 (0.2)	1	0.1	0		
No	0			2 (0.5)	2	0.4
Facial bones fracture						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Femur fracture						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Fractured coccyx						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Spinal compression fracture						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Stress fracture						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Upper limb fracture						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Thoracic vertebral fracture						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tibia fracture						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Wrist fracture						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Fibula fracture						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Torus fracture						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Procedural related injuries and complications NEC						
Yes	14 (2.8)	19	2.8	4 (1.8)	4	1.4
No	13 (1.6)	16	1.5	7 (1.6)	9	1.7
Procedural pain						
Yes	7 (1.4)	8	1.2	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	6 (1.4)	8	1.5
Injection related reaction						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	0		
Post procedural complication						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	3	0.3	0		
Administration related reaction						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Procedural nausea						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Anaemia postoperative						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Post procedural constipation						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Post procedural haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Procedural haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Urinary retention postoperative						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Anaphylactic transfusion reaction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Suture related complication						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaccination complication						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Procedural vomiting						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Seroma						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Medication errors and other product use errors and issues						
Yes	3 (0.6)	3	0.4	1 (0.4)	2	0.7
No	7 (0.9)	7	0.7	1 (0.2)	1	0.2
Accidental overdose						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Incorrect dose administered						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Medication error						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Injuries by physical agents						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	4 (0.5)	4	0.4	2 (0.5)	2	0.4
Sunburn						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Heat exhaustion						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Heat illness						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hypobarism						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Thermal burn						
Yes	0			2	(0.9)	2 0.7
No	1	(0.1)	1 <0.1	0		
Burns second degree						
Yes	0			1	(0.4)	1 0.3
No	0			2	(0.5)	2 0.4
Overdoses and underdoses NEC						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	3	(0.4)	3 0.3	1	(0.2)	1 0.2
Overdose						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	3	(0.4)	3 0.3	1	(0.2)	1 0.2
Exposures, chemical injuries and poisoning						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Reactive gastropathy						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Exposure to toxic agent						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Skin and subcutaneous tissue disorders						
Yes	73	(14.6)	91 13.6	26	(11.5)	34 11.5
No	115	(14.3)	158 15.2	49	(11.4)	62 11.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Epidermal and dermal conditions						
Yes	44 (8.8)	50	7.5	14 (6.2)	19	6.4
No	61 (7.6)	79	7.6	38 (8.9)	46	8.6
Rash						
Yes	12 (2.4)	13	1.9	6 (2.7)	8	2.7
No	14 (1.7)	17	1.6	11 (2.6)	15	2.8
Pruritus						
Yes	7 (1.4)	8	1.2	1 (0.4)	1	0.3
No	10 (1.2)	10	1.0	5 (1.2)	5	0.9
Eczema						
Yes	6 (1.2)	6	0.9	0		
No	7 (0.9)	7	0.7	4 (0.9)	4	0.7
Dry skin						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Skin burning sensation						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	5 (0.6)	11	1.1	1 (0.2)	1	0.2
Dermatitis contact						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	4 (0.5)	6	0.6	2 (0.5)	2	0.4
Skin lesion						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Erythema						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Psoriasis						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Pain of skin						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Rash pruritic						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Skin irritation						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Blister						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	0			3 (0.7)	3	0.6
Dermatitis						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Decubitus ulcer						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Skin disorder						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	2	0.2	1 (0.2)	1	0.2
Dermatitis allergic						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Dermatitis atopic						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Papule						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Perioral dermatitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Prurigo						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Skin discolouration						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Macule						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pityriasis rosea						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Rash maculo-papular						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin odour abnormal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Xanthelasma						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Drug eruption						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Photosensitivity reaction						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Rash erythematous						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Rash macular						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Skin reaction						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Skin appendage conditions						
Yes	26	(5.2)	28 4.2	10	(4.4)	11 3.7
No	56	(6.9)	64 6.2	9	(2.1)	10 1.9
Alopecia						
Yes	14	(2.8)	15 2.2	2	(0.9)	2 0.7
No	39	(4.8)	40 3.9	3	(0.7)	3 0.6
Hyperhidrosis						
Yes	5	(1.0)	5 0.7	5	(2.2)	5 1.7
No	3	(0.4)	3 0.3	3	(0.7)	3 0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Ingrowing nail						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	1 (0.1)	1	<0.1	0		
Acne						
Yes	0			1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Miliaria						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Cold sweat						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Hirsutism						
Yes	0			0		
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Hair growth abnormal						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Rosacea						
Yes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hidradenitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Hypertrichosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Diffuse alopecia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nail bed inflammation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nail discolouration						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Night sweats						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Onychoclasis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Angioedema and urticaria						
Yes	5 (1.0)	5	0.7	3 (1.3)	3	1.0
No	8 (1.0)	8	0.8	3 (0.7)	3	0.6
Urticaria						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	8 (1.0)	8	0.8	2 (0.5)	2	0.4
Cold urticaria						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Angioedema						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cornification and dystrophic skin disorders						
Yes	5 (1.0)	7	1.0	0		
No	2 (0.2)	2	0.2	0		
Actinic keratosis						
Yes	3 (0.6)	4	0.6	0		
No	0			0		
Hyperkeratosis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Lichenoid keratosis						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Skin striae						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pigmentation disorders						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Ephelides						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Skin hyperpigmentation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cutaneous neoplasms benign						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Dermal cyst						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Skin vascular abnormalities						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Ecchymosis						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Skin and subcutaneous tissue disorders NEC						
Yes	0			0		
No	0			2 (0.5)	2	0.4
Erythema nodosum						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skin ulcer						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Respiratory, thoracic and mediastinal disorders						
Yes	61 (12.2)	78	11.7	38 (16.8)	51	17.3
No	112 (13.9)	147	14.2	66 (15.4)	83	15.5
Respiratory tract signs and symptoms						
Yes	28 (5.6)	29	4.3	14 (6.2)	16	5.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	47 (5.8)	52	5.0	19 (4.4)	21	3.9
Oropharyngeal pain						
Yes	16 (3.2)	17	2.5	9 (4.0)	10	3.4
No	32 (4.0)	36	3.5	14 (3.3)	16	3.0
Rhinorrhoea						
Yes	4 (0.8)	4	0.6	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Upper respiratory tract inflammation						
Yes	3 (0.6)	3	0.4	4 (1.8)	4	1.4
No	2 (0.2)	3	0.3	0		
Hiccups						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Upper-airway cough syndrome						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Catarrh						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Dysphonia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Oropharyngeal discomfort						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Diaphragmalgia						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Paranasal sinus discomfort						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Pleuritic pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sinus pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Yawning						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Upper respiratory tract congestion						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Respiratory disorders NEC						
Yes	21 (4.2)	23	3.4	16 (7.1)	17	5.8
No	40 (5.0)	47	4.5	35 (8.2)	39	7.3
Cough						
Yes	12 (2.4)	13	1.9	10 (4.4)	11	3.7
No	28 (3.5)	32	3.1	23 (5.4)	24	4.5
Dyspnoea						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	7 (1.6)	7	1.3
Sleep apnoea syndrome						
Yes	3 (0.6)	3	0.4	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Dyspnoea exertional						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Haemoptysis						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Productive cough						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Respiratory disorder						
Yes	0			2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Respiratory tract congestion						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hyperventilation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Acute respiratory failure						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Pulmonary mass						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Upper respiratory tract disorders (excl infections)						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	17 (3.4)	18	2.7	8 (3.5)	9	3.1
No	34 (4.2)	35	3.4	10 (2.3)	12	2.2
Sinus congestion						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	10 (1.2)	10	1.0	3 (0.7)	5	0.9
Nasal congestion						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	7 (0.9)	7	0.7	4 (0.9)	4	0.7
Rhinitis allergic						
Yes	2 (0.4)	2	0.3	4 (1.8)	5	1.7
No	9 (1.1)	9	0.9	2 (0.5)	2	0.4
Epistaxis						
Yes	3 (0.6)	3	0.4	0		
No	4 (0.5)	4	0.4	0		
Nasal polyps						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Nasal septum deviation						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Paranasal sinus hypersecretion						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Tonsillar hypertrophy						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Nasal dryness						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Vocal cord polyp						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Paranasal cyst						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nasal adhesions						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Bronchial disorders (excl neoplasms)						
Yes	6 (1.2)	6	0.9	5 (2.2)	8	2.7
No	8 (1.0)	8	0.8	8 (1.9)	8	1.5
Asthma						
Yes	3 (0.6)	3	0.4	3 (1.3)	5	1.7
No	8 (1.0)	8	0.8	6 (1.4)	6	1.1
Chronic obstructive pulmonary disease						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Wheezing						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Allergic bronchitis						
Yes	0			1 (0.4)	2	0.7
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Lower respiratory tract disorders (excl obstruction and infection)						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Atelectasis						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Pulmonary fibrosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pleural disorders						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Pleural effusion						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Pleurisy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Pulmonary vascular disorders						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Pulmonary embolism						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Psychiatric disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	51 (10.2)	72	10.8	26 (11.5)	32	10.9
No	73 (9.0)	88	8.5	57 (13.3)	81	15.1
Anxiety disorders and symptoms						
Yes	21 (4.2)	21	3.1	8 (3.5)	8	2.7
No	25 (3.1)	27	2.6	23 (5.4)	24	4.5
Anxiety						
Yes	17 (3.4)	17	2.5	5 (2.2)	5	1.7
No	15 (1.9)	16	1.5	15 (3.5)	15	2.8
Stress						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Panic attack						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Acute stress disorder						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Post-traumatic stress disorder						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Burnout syndrome						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nervousness						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Agitation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			2 (0.5)	2	0.4
Generalised anxiety disorder						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Sleep disorders and disturbances						
Yes	18 (3.6)	19	2.8	12 (5.3)	12	4.1
No	22 (2.7)	23	2.2	17 (4.0)	21	3.9
Insomnia						
Yes	14 (2.8)	14	2.1	8 (3.5)	8	2.7
No	14 (1.7)	15	1.4	10 (2.3)	11	2.1
Sleep disorder						
Yes	1 (0.2)	1	0.1	3 (1.3)	3	1.0
No	5 (0.6)	5	0.5	4 (0.9)	5	0.9
Initial insomnia						
Yes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Abnormal dreams						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Middle insomnia						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Nightmare						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	3	0.6
Sleep terror						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Depressed mood disorders and disturbances						
Yes	14 (2.8)	17	2.5	6 (2.7)	6	2.0
No	19 (2.4)	22	2.1	21 (4.9)	23	4.3
Depression						
Yes	5 (1.0)	6	0.9	2 (0.9)	2	0.7
No	10 (1.2)	11	1.1	12 (2.8)	13	2.4
Depressed mood						
Yes	6 (1.2)	6	0.9	3 (1.3)	3	1.0
No	8 (1.0)	9	0.9	6 (1.4)	6	1.1
Major depression						
Yes	3 (0.6)	3	0.4	0		
No	0			0		
Anhedonia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Negative thoughts						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Tearfulness						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Depressive symptom						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Persistent depressive disorder						
Yes	0			1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Mood disorders and disturbances NEC						
Yes	5 (1.0)	5	0.7	0		
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Irritability						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Apathy						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Affective disorder						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Mood swings						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sexual dysfunctions, disturbances and gender identity disorders						
Yes	3 (0.6)	3	0.4	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Libido decreased						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Libido increased						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Changes in physical activity						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	0		
Restlessness						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Tic						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Suicidal and self-injurious behaviours NEC						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	3 (0.7)	5	0.9
Suicidal ideation						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	2 (0.5)	4	0.7
Suicide attempt						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Adjustment disorders (incl subtypes)						
Yes	1 (0.2)	1	0.1	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Grief reaction						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Adjustment disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Adjustment disorder with depressed mood						
Yes	0			3	(1.3)	3 1.0
No	1	(0.1)	1 <0.1	0		
Cognitive and attention disorders and disturbances						
Yes	1	(0.2)	2 0.3	0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Mental fatigue						
Yes	1	(0.2)	2 0.3	0		
No	0			0		
Attention deficit/hyperactivity disorder						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Manic and bipolar mood disorders and disturbances						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Bipolar disorder						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Psychiatric and behavioural symptoms NEC						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Abulia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Psychiatric symptom						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Deliria (incl confusion)						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	2	0.2	0		
Disorientation						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	2	0.2	0		
Psychiatric disorders NEC						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Alcoholic hangover						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Somatic symptom and related disorders						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Conversion disorder						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Vascular disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	47 (9.4)	52	7.8	19 (8.4)	20	6.8
No	43 (5.3)	45	4.3	26 (6.1)	30	5.6
Vascular hypertensive disorders						
Yes	21 (4.2)	21	3.1	12 (5.3)	13	4.4
No	21 (2.6)	21	2.0	16 (3.7)	19	3.6
Hypertension						
Yes	20 (4.0)	20	3.0	12 (5.3)	13	4.4
No	20 (2.5)	20	1.9	15 (3.5)	18	3.4
Essential hypertension						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hypertensive emergency						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hypertensive crisis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Decreased and nonspecific blood pressure disorders and shock						
Yes	10 (2.0)	12	1.8	1 (0.4)	1	0.3
No	9 (1.1)	9	0.9	1 (0.2)	1	0.2
Hypotension						
Yes	6 (1.2)	7	1.0	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Orthostatic hypotension						
Yes	4 (0.8)	5	0.7	0		
No	4 (0.5)	4	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Circulatory collapse						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vascular disorders NEC						
Yes	6 (1.2)	7	1.0	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Hot flush						
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Flushing						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Vascular haemorrhagic disorders						
Yes	4 (0.8)	4	0.6	4 (1.8)	4	1.4
No	2 (0.2)	2	0.2	0		
Haematoma						
Yes	4 (0.8)	4	0.6	4 (1.8)	4	1.4
No	2 (0.2)	2	0.2	0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis						
Yes	2 (0.4)	2	0.3	0		
No	5 (0.6)	5	0.5	4 (0.9)	4	0.7
Peripheral venous disease						
Yes	0			0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Peripheral coldness						
Yes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Aortic arteriosclerosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Arteriosclerosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Raynaud's phenomenon						
Yes	0			0		
No	0			3 (0.7)	3	0.6
Venous varices						
Yes	3 (0.6)	3	0.4	0		
No	3 (0.4)	3	0.3	0		
Varicose vein						
Yes	3 (0.6)	3	0.4	0		
No	3 (0.4)	3	0.3	0		
Embolism and thrombosis						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Thrombosis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Thrombophlebitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Deep vein thrombosis						
Yes	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Thrombophlebitis superficial						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Vascular infections and inflammations						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Arteritis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Phlebitis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Lymphatic vessel disorders						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Lymphoedema						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Investigations						
Yes	37 (7.4)	44	6.6	12 (5.3)	14	4.7
No	56 (6.9)	74	7.1	37 (8.6)	53	9.9
Hepatobiliary investigations						
Yes	8 (1.6)	9	1.3	3 (1.3)	4	1.4
No	8 (1.0)	8	0.8	8 (1.9)	11	2.1
Gamma-glutamyltransferase increased						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	6 (1.2)	6	0.9	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Hepatic enzyme increased						
Yes	1 (0.2)	1	0.1	0		
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Alanine aminotransferase increased						
Yes	1 (0.2)	1	0.1	0		
No	0			3 (0.7)	3	0.6
Aspartate aminotransferase increased						
Yes	1 (0.2)	1	0.1	0		
No	0			4 (0.9)	4	0.7
Blood bilirubin increased						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Transaminases increased						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Gastrointestinal investigations						
Yes	5 (1.0)	6	0.9	1 (0.4)	1	0.3
No	8 (1.0)	9	0.9	1 (0.2)	1	0.2
Lipase increased						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	7 (0.9)	7	0.7	1 (0.2)	1	0.2
Amylase increased						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Gastric pH						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Pancreatic enzymes increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Protein and chemistry analyses NEC						
Yes	1 (0.2)	1	0.1	0		
No	12 (1.5)	12	1.2	5 (1.2)	5	0.9
C-reactive protein increased						
Yes	1 (0.2)	1	0.1	0		
No	12 (1.5)	12	1.2	5 (1.2)	5	0.9
Cardiac and vascular investigations (excl enzyme tests)						
Yes	5 (1.0)	6	0.9	1 (0.4)	1	0.3
No	5 (0.6)	6	0.6	6 (1.4)	6	1.1
QRS axis abnormal						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Heart rate increased						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Blood pressure abnormal						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Blood pressure decreased						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood pressure increased						
Yes	1 (0.2)	1	0.1	0		
No	0			6 (1.4)	6	1.1
Cardiac murmur						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Pulse abnormal						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Electrocardiogram ST segment depression						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave amplitude decreased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave inversion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave abnormal						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Endocrine investigations (incl sex hormones)						
Yes	3 (0.6)	3	0.4	0		
No	5 (0.6)	7	0.7	3 (0.7)	3	0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood calcitonin increased						
Yes	3 (0.6)	3	0.4	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Blood thyroid stimulating hormone decreased						
Yes	0			0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Blood thyroid stimulating hormone abnormal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Thyroxine free increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Thyroxine increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blood thyroid stimulating hormone increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Lipid analyses						
Yes	1 (0.2)	3	0.4	0		
No	8 (1.0)	13	1.3	4 (0.9)	5	0.9
High density lipoprotein decreased						
Yes	1 (0.2)	1	0.1	0		
No	4 (0.5)	4	0.4	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood cholesterol increased						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Low density lipoprotein increased						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Lipids increased						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Blood triglycerides increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Very low density lipoprotein increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Physical examination and organ system status topics						
Yes	3 (0.6)	3	0.4	2 (0.9)	3	1.0
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Weight decreased						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Weight increased						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Body mass index decreased						

Adverse events with onset prior to randomisation are not included.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Respiratory rate increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Body temperature increased						
Yes	0			1 (0.4)	2	0.7
No	0			0		
Enzyme investigations NEC						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	6 (1.4)	6	1.1
Blood creatine phosphokinase increased						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	6 (1.4)	6	1.1
Enzyme level increased						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Blood alkaline phosphatase increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Renal and urinary tract investigations and urinalyses						
Yes	3 (0.6)	3	0.4	0		
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Blood creatinine increased						
Yes	2 (0.4)	2	0.3	0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
White blood cells urine						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Glomerular filtration rate decreased						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Blood urine present						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Microbiology and serology investigations						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	0		
HIV test positive						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Helicobacter test positive						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Human papilloma virus test positive						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Haematology investigations (incl blood groups)						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	2 (0.5)	5	0.9

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Haemoglobin decreased						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Haematology test abnormal						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Haematocrit increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Haemoglobin increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Red blood cell count increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Red cell distribution width increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Cytogenetic investigations						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Prostatic specific antigen increased						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Investigations, imaging and histopathology procedures NEC						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Precancerous cells present						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Smear test						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Endoscopy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Metabolic, nutritional and blood gas investigations						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Blood uric acid increased						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Blood glucose increased						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Glycosylated haemoglobin increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Vitamin D decreased						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Water, electrolyte and mineral investigations						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Blood calcium decreased						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Blood potassium increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blood iron decreased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Blood sodium increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Serum ferritin decreased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Reproductive organ and breast investigations (excl hormone analyses)						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Biopsy breast						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and soft tissue investigations (excl enzyme tests)						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Arthroscopy						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Immunology and allergy investigations						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Antinuclear antibody positive						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Reproductive system and breast disorders						
Yes	26 (5.2)	29	4.3	10 (4.4)	13	4.4
No	70 (8.7)	93	9.0	22 (5.1)	26	4.9
Menstrual cycle and uterine bleeding disorders						
Yes	9 (1.8)	10	1.5	3 (1.3)	6	2.0
No	36 (4.5)	43	4.1	4 (0.9)	4	0.7
Menstruation irregular						
Yes	3 (0.6)	3	0.4	0		
No	11 (1.4)	11	1.1	0		
Menorrhagia						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	9 (1.1)	11	1.1	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Dysmenorrhoea						
Yes	3 (0.6)	3	0.4	1 (0.4)	3	1.0
No	4 (0.5)	5	0.5	0		
Metrorrhagia						
Yes	1 (0.2)	1	0.1	0		
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Menstrual disorder						
Yes	0			0		
No	5 (0.6)	5	0.5	0		
Dysfunctional uterine bleeding						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Oligomenorrhoea						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Amenorrhoea						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Menstruation delayed						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Premenstrual syndrome						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Premenstrual pain						
Yes	0			1 (0.4)	1	0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast disorders						
Yes	7 (1.4)	7	1.0	1 (0.4)	1	0.3
No	10 (1.2)	13	1.3	6 (1.4)	7	1.3
Breast mass						
Yes	1 (0.2)	1	0.1	0		
No	7 (0.9)	7	0.7	1 (0.2)	2	0.4
Breast cyst						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Breast disorder						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Breast pain						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Fibrocystic breast disease						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Breast inflammation						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Nipple pain						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Breast fibrosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast haematoma						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Uterine, pelvic and broad ligament disorders						
Yes	2 (0.4)	2	0.3	0		
No	9 (1.1)	9	0.9	2 (0.5)	2	0.4
Uterine haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Adenomyosis						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Endometriosis						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Uterine polyp						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Uterine enlargement						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaginal prolapse						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Menopause related conditions						
Yes	5 (1.0)	5	0.7	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	4 (0.5)	4	0.4	3 (0.7)	4	0.7
Atrophic vulvovaginitis						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Menopausal symptoms						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Postmenopausal haemorrhage						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Vulvovaginal disorders (excl infections and inflammations)						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	7 (0.9)	7	0.7	3 (0.7)	3	0.6
Vaginal haemorrhage						
Yes	1 (0.2)	1	0.1	0		
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Vulvovaginal dryness						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Vulvovaginal discomfort						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vulvovaginal pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaginal polyp						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.4)	1 0.3
No	0			0		
Vulvovaginal pruritus						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Ovarian and fallopian tube disorders						
Yes	0			0		
No	9	(1.1)	9 0.9	3	(0.7)	3 0.6
Ovarian cyst						
Yes	0			0		
No	7	(0.9)	7 0.7	2	(0.5)	2 0.4
Hydrosalpinx						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Polycystic ovaries						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Reproductive tract disorders NEC						
Yes	0			0		
No	3	(0.4)	3 0.3	1	(0.2)	1 0.2
Pelvic pain						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Genital rash						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Genital pain						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	0			1	(0.2)	1 0.2
Cervix disorders (excl infections and inflammations)						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Cervical leukoplakia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Cervical dysplasia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Uterine cervical erosion						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Testicular and epididymal disorders						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Testicular pain						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Testicular mass						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Testicular disorder						
Yes	0			0		
No	0			1	(0.2)	1 0.2

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Sexual function and fertility disorders						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Dyspareunia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Erectile dysfunction						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Prostatic disorders (excl infections and inflammations)						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	0			0		
Benign prostatic hyperplasia						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	0			0		
Female reproductive tract infections and inflammations						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Uterine inflammation						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Penile and scrotal disorders (excl infections and inflammations)						
Yes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Scrotal pain						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Cardiac disorders						
Yes	25 (5.0)	28	4.2	12 (5.3)	16	5.4
No	29 (3.6)	34	3.3	21 (4.9)	28	5.2
Cardiac arrhythmias						
Yes	17 (3.4)	19	2.8	6 (2.7)	8	2.7
No	15 (1.9)	19	1.8	11 (2.6)	13	2.4
Atrial fibrillation						
Yes	5 (1.0)	5	0.7	1 (0.4)	2	0.7
No	1 (0.1)	4	0.4	2 (0.5)	2	0.4
Atrioventricular block first degree						
Yes	3 (0.6)	3	0.4	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Tachycardia						
Yes	3 (0.6)	3	0.4	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	4 (0.9)	4	0.7
Bundle branch block left						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Ventricular extrasystoles						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Arrhythmia						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	2	(0.2)	2 0.2	2	(0.5)	2 0.4
Sinus tachycardia						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Atrial flutter						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Atrial tachycardia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Atrioventricular block						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Bradycardia						
Yes	1	(0.2)	1 0.1	0		
No	0			3	(0.7)	3 0.6
Defect conduction intraventricular						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Nodal rhythm						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Atrioventricular block second degree						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Bundle branch block right						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			2	(0.9)	2 0.7
No	1	(0.1)	1 <0.1	0		
Cardiac flutter						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Sinus bradycardia						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Supraventricular extrasystoles						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Cardiac disorders, signs and symptoms NEC						
Yes	3	(0.6)	3 0.4	2	(0.9)	2 0.7
No	9	(1.1)	9 0.9	6	(1.4)	8 1.5
Palpitations						
Yes	3	(0.6)	3 0.4	1	(0.4)	1 0.3
No	7	(0.9)	7 0.7	5	(1.2)	7 1.3
Cardiovascular disorder						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Hypertensive heart disease						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Coronary artery disorders						
Yes	4	(0.8)	4 0.6	2	(0.9)	3 1.0
No	3	(0.4)	3 0.3	5	(1.2)	5 0.9

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Angina pectoris						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Acute myocardial infarction						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Angina unstable						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Arteriosclerosis coronary artery						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Coronary artery stenosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Coronary artery disease						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Myocardial infarction						
Yes	0			0		
No	0			2 (0.5)	2	0.4
Cardiac valve disorders						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Aortic valve sclerosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Aortic valve incompetence						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Mitral valve incompetence						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Tricuspid valve incompetence						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Cardiac neoplasms						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Pericardial cyst						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Myocardial disorders						
Yes	0			3	(1.3)	3 1.0
No	1	(0.1)	1 <0.1	0		
Left ventricular hypertrophy						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Cardiomegaly						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Cardiomyopathy						
Yes	0			1	(0.4)	1 0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Myocarditis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Pericardial disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pericardial disease						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Yes	21 (4.2)	24	3.6	9 (4.0)	11	3.7
No	25 (3.1)	28	2.7	16 (3.7)	16	3.0
Cutaneous neoplasms benign						
Yes	4 (0.8)	6	0.9	5 (2.2)	5	1.7
No	6 (0.7)	8	0.8	1 (0.2)	1	0.2
Melanocytic naevus						
Yes	4 (0.8)	5	0.7	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Acrochordon						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Seborrhoeic keratosis						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Dysplastic naevus						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin papilloma						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Pyogenic granuloma						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Reproductive neoplasms female benign						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	4 (0.9)	4	0.7
Uterine leiomyoma						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	4 (0.9)	4	0.7
Ovarian adenoma						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Soft tissue neoplasms benign						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	0		
Lipoma						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	0		
Leiomyoma						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast neoplasms malignant and unspecified (incl nipple)						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Intraductal proliferative breast lesion						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Breast cancer						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Invasive ductal breast carcinoma						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lobular breast carcinoma in situ						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Phyllodes tumour						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skin neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Basal cell carcinoma						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Malignant melanoma						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Malignant melanoma in situ						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Neoplasm skin						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Gastrointestinal neoplasms benign						
Yes	1	(0.2)	1 0.1	0		
No	2	(0.2)	2 0.2	0		
Colon adenoma						
Yes	1	(0.2)	1 0.1	0		
No	2	(0.2)	2 0.2	0		
Miscellaneous and site unspecified neoplasms malignant and unspecified						
Yes	2	(0.4)	2 0.3	0		
No	0			0		
Neoplasm						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Squamous cell carcinoma						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Breast neoplasms benign (incl nipple)						
Yes	1	(0.2)	1 0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Benign breast neoplasm						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Endocrine neoplasms benign						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Benign neoplasm of thyroid gland						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Parathyroid tumour benign						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hepatic and biliary neoplasms benign						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Haemangioma of liver						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Endocrine neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Papillary thyroid cancer						
Yes	1 (0.2)	1	0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Gastrointestinal stromal tumour						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hepatobiliary neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hepatic neoplasm						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Reproductive neoplasms male malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Prostate cancer						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Soft tissue neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Dermatofibrosarcoma protuberans						
Yes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	0				0			
Miscellaneous and site unspecified neoplasms benign								
Yes	0				1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Fibroma								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Adenoma benign								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Reproductive neoplasms female malignant and unspecified								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Cervix carcinoma stage 0								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Skeletal neoplasms benign								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Haemangioma of bone								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Leukaemias								
Yes	0				1	(0.4)	1	0.3
No	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hairy cell leukaemia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Nervous system neoplasms malignant and unspecified NEC						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Glioblastoma						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Ocular neoplasms						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Eyelid haemangioma						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Plasma cell neoplasms						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Paraproteinaemia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Renal and urinary tract neoplasms benign						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Kidney angiomyolipoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Renal and urinary tract neoplasms malignant and unspecified						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Urinary tract neoplasm						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Eye disorders						
Yes	19 (3.8)	25	3.7	8 (3.5)	11	3.7
No	25 (3.1)	33	3.2	16 (3.7)	20	3.7
Vision disorders						
Yes	5 (1.0)	6	0.9	0		
No	9 (1.1)	11	1.1	4 (0.9)	4	0.7
Vision blurred						
Yes	1 (0.2)	1	0.1	0		
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Diplopia						
Yes	2 (0.4)	3	0.4	0		
No	1 (0.1)	1	<0.1	0		
Myopia						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Anisometropia						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Astigmatism						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Photopsia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Visual impairment						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Scintillating scotoma						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Ocular infections, irritations and inflammations						
Yes	3 (0.6)	4	0.6	3 (1.3)	5	1.7
No	5 (0.6)	6	0.6	4 (0.9)	5	0.9
Eye pruritus						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Conjunctivitis allergic						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Eye discharge						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Ocular hyperaemia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Conjunctival irritation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eczema eyelids						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eye allergy						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Meibomian gland dysfunction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Swelling of eyelid						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blepharitis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Conjunctival hyperaemia						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Erythema of eyelid						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Eye inflammation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	2	0.7
No	0			0		
Eye irritation						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Keratitis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Ulcerative keratitis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Anterior eye structural change, deposit and degeneration						
Yes	4 (0.8)	4	0.6	2 (0.9)	3	1.0
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Cataract						
Yes	3 (0.6)	3	0.4	1 (0.4)	2	0.7
No	3 (0.4)	4	0.4	0		
Xerophthalmia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Ectropion						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Pterygium						
Yes	0			1 (0.4)	1	0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Eye disorders NEC						
Yes	2	(0.4)	2 0.3	2	(0.9)	2 0.7
No	6	(0.7)	6 0.6	4	(0.9)	4 0.7
Dry eye						
Yes	2	(0.4)	2 0.3	2	(0.9)	2 0.7
No	2	(0.2)	2 0.2	2	(0.5)	2 0.4
Eyelid disorder						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Eye pain						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Lacrimation increased						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Ocular discomfort						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Ocular structural change, deposit and degeneration NEC						
Yes	3	(0.6)	4 0.6	1	(0.4)	1 0.3
No	0			1	(0.2)	1 0.2
Macular degeneration						
Yes	3	(0.6)	4 0.6	0		
No	0			0		
Vitreous detachment						
Yes	0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Glaucoma and ocular hypertension						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	2	0.4
Glaucoma						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	2	0.4
Ocular haemorrhages and vascular disorders NEC						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Optic ischaemic neuropathy						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Eyelid haematoma						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Conjunctival haemorrhage						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Retina, choroid and vitreous haemorrhages and vascular disorders						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Retinopathy						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Retinal aneurysm						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Ocular sensory symptoms NEC						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Asthenopia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Ocular neuromuscular disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Blepharospasm						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hepatobiliary disorders						
Yes	18 (3.6)	23	3.4	8 (3.5)	9	3.1
No	26 (3.2)	33	3.2	5 (1.2)	5	0.9
Gallbladder disorders						
Yes	15 (3.0)	19	2.8	2 (0.9)	2	0.7
No	16 (2.0)	19	1.8	3 (0.7)	3	0.6
Cholelithiasis						
Yes	11 (2.2)	12	1.8	2 (0.9)	2	0.7
No	12 (1.5)	12	1.2	2 (0.5)	2	0.4
Cholecystitis acute						
Yes	3 (0.6)	3	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Cholecystitis						
Yes	1 (0.2)	1	0.1	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Gallbladder disorder						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Cholecystitis chronic						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Biliary dyskinesia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hepatic and hepatobiliary disorders						
Yes	3 (0.6)	3	0.4	7 (3.1)	7	2.4
No	10 (1.2)	13	1.3	2 (0.5)	2	0.4
Hepatic steatosis						
Yes	1 (0.2)	1	0.1	5 (2.2)	5	1.7
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Hepatic function abnormal						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Hepatic cyst						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Granulomatous liver disease						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Hepatic pain						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Hypertransaminasaemia						
Yes	0			0		
No	1	(0.1)	3 0.3	0		
Nonalcoholic fatty liver disease						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Portal vein thrombosis						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Bile duct disorders						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Biliary colic						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Bile duct stone						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Ear and labyrinth disorders						
Yes	15	(3.0)	19 2.8	10	(4.4)	12 4.1
No	30	(3.7)	37 3.6	14	(3.3)	17 3.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Inner ear and VIIIth cranial nerve disorders						
Yes	8 (1.6)	11	1.6	8 (3.5)	10	3.4
No	14 (1.7)	15	1.4	10 (2.3)	12	2.2
Vertigo						
Yes	6 (1.2)	6	0.9	5 (2.2)	6	2.0
No	11 (1.4)	11	1.1	7 (1.6)	7	1.3
Tinnitus						
Yes	2 (0.4)	3	0.4	0		
No	1 (0.1)	1	<0.1	2 (0.5)	3	0.6
Vertigo positional						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	2 (0.2)	3	0.3	1 (0.2)	2	0.4
Meniere's disease						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Motion sickness						
Yes	0			1 (0.4)	2	0.7
No	0			0		
Aural disorders NEC						
Yes	3 (0.6)	3	0.4	0		
No	12 (1.5)	13	1.3	2 (0.5)	2	0.4
Ear pain						
Yes	3 (0.6)	3	0.4	0		
No	9 (1.1)	10	1.0	2 (0.5)	2	0.4
Ear discomfort						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	2	(0.2)	2 0.2	0		
Ear congestion						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Middle ear disorders (excl congenital)						
Yes	2	(0.4)	2 0.3	2	(0.9)	2 0.7
No	4	(0.5)	5 0.5	0		
Eustachian tube dysfunction						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	3	(0.4)	4 0.4	0		
Eustachian tube disorder						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Tympanic membrane disorder						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Hearing disorders						
Yes	2	(0.4)	2 0.3	0		
No	2	(0.2)	2 0.2	2	(0.5)	2 0.4
Deafness neurosensory						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Hypoacusis						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Sudden hearing loss						
Yes	1	(0.2)	1 0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Deafness						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hyperacusis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
External ear disorders (excl congenital)						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Cerumen impaction						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Excessive cerumen production						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Renal and urinary disorders						
Yes	16 (3.2)	21	3.1	10 (4.4)	11	3.7
No	25 (3.1)	30	2.9	12 (2.8)	13	2.4
Urinary tract signs and symptoms						
Yes	8 (1.6)	8	1.2	2 (0.9)	2	0.7
No	18 (2.2)	21	2.0	6 (1.4)	7	1.3
Dysuria						
Yes	2 (0.4)	2	0.3	0		
No	7 (0.9)	9	0.9	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Haematuria						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Chromaturia						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Stress urinary incontinence						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Pollakiuria						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Renal pain						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Bladder pain						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Urine odour abnormal						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Micturition urgency						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Nocturia						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Renal colic						
Yes	0			0		
No	1	(0.1)	2 0.2	0		
Urine flow decreased						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Polyuria						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Urinary incontinence						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Urinary retention						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Urolithiases						
Yes	5	(1.0)	6 0.9	3	(1.3)	3 1.0
No	6	(0.7)	6 0.6	3	(0.7)	3 0.6
Nephrolithiasis						
Yes	3	(0.6)	3 0.4	3	(1.3)	3 1.0
No	5	(0.6)	5 0.5	3	(0.7)	3 0.6
Calculus urinary						
Yes	2	(0.4)	2 0.3	0		
No	1	(0.1)	1 <0.1	0		
Ureterolithiasis						
Yes	1	(0.2)	1 0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Renal disorders (excl nephropathies)						
Yes	5 (1.0)	7	1.0	5 (2.2)	6	2.0
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Acute kidney injury						
Yes	3 (0.6)	3	0.4	1 (0.4)	1	0.3
No	0			0		
Renal cyst						
Yes	1 (0.2)	1	0.1	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Chronic kidney disease						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Hydronephrosis						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Renal impairment						
Yes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
No	0			0		
Nephrectasia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hypertensive nephropathy						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bladder and bladder neck disorders (excl calculi)						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Cystitis noninfective						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Urethral disorders (excl calculi)						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Urethritis noninfective						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Blood and lymphatic system disorders						
Yes	15	(3.0)	17 2.5	8	(3.5)	11 3.7
No	20	(2.5)	20 1.9	8	(1.9)	10 1.9
Anaemias nonhaemolytic and marrow depression						
Yes	11	(2.2)	12 1.8	4	(1.8)	4 1.4
No	13	(1.6)	13 1.3	6	(1.4)	7 1.3
Anaemia						
Yes	9	(1.8)	10 1.5	3	(1.3)	3 1.0
No	10	(1.2)	10 1.0	6	(1.4)	7 1.3
Iron deficiency anaemia						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Blood loss anaemia						
Yes	1	(0.2)	1 0.1	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hypochromic anaemia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Pernicious anaemia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Pancytopenia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Spleen, lymphatic and reticuloendothelial system disorders						
Yes	2	(0.4)	2 0.3	2	(0.9)	3 1.0
No	5	(0.6)	5 0.5	1	(0.2)	1 0.2
Lymphadenopathy						
Yes	1	(0.2)	1 0.1	1	(0.4)	2 0.7
No	3	(0.4)	3 0.3	0		
Splenomegaly						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	0			1	(0.2)	1 0.2
Hypersplenism						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Splenic haemorrhage						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
White blood cell disorders						
Yes	3	(0.6)	3 0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Leukocytosis						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Eosinophilia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Platelet disorders						
Yes	0			3 (1.3)	3	1.0
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Thrombocytopenia						
Yes	0			3 (1.3)	3	1.0
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Red blood cell disorders						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Polycythaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Microcytosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Immune system disorders						
Yes	13 (2.6)	13	1.9	6 (2.7)	7	2.4
No	15 (1.9)	15	1.4	15 (3.5)	16	3.0
Allergic conditions						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	13 (2.6)	13	1.9	6 (2.7)	7	2.4
No	14 (1.7)	14	1.3	15 (3.5)	16	3.0
Seasonal allergy						
Yes	6 (1.2)	6	0.9	4 (1.8)	4	1.4
No	9 (1.1)	9	0.9	10 (2.3)	10	1.9
Allergy to arthropod bite						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Hypersensitivity						
Yes	1 (0.2)	1	0.1	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Drug hypersensitivity						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Food allergy						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	0		
Allergy to arthropod sting						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Rubber sensitivity						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Mite allergy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Multiple allergies						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	0			1	(0.2)	1 0.2
Immune disorders NEC						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Immunisation reaction						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Surgical and medical procedures						
Yes	7	(1.4)	7 1.0	2	(0.9)	2 0.7
No	11	(1.4)	12 1.2	6	(1.4)	6 1.1
Head and neck therapeutic procedures						
Yes	2	(0.4)	2 0.3	0		
No	4	(0.5)	4 0.4	1	(0.2)	1 0.2
Tooth extraction						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Dental operation						
Yes	0			0		
No	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Sinus operation						
Yes	1	(0.2)	1 0.1	0		
No	0			0		
Dental implantation						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Therapeutic procedures and supportive care NEC						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Polypectomy						
Yes	1 (0.2)	1	0.1	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Spinal anaesthesia						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Cyst removal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin and subcutaneous tissue therapeutic procedures						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Acrochordon excision						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin neoplasm excision						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eye therapeutic procedures						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Glaucoma surgery						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Hepatobiliary therapeutic procedures						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Cholecystectomy						
Yes	1 (0.2)	1	0.1	0		
No	0			1 (0.2)	1	0.2
Nervous system, skull and spine therapeutic procedures						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Intervertebral disc operation						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Bone and joint therapeutic procedures						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Synovial cyst removal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Bone prosthesis insertion						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Hip surgery						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Gastrointestinal therapeutic procedures						
Yes	0			0		
No	1	(0.1)	1 <0.1	2	(0.5)	2 0.4
Gastric bypass						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Abdominoplasty						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Obstetric and gynaecological therapeutic procedures						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Abortion induced						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Ovarian operation						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Soft tissue therapeutic procedures						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Lipoma excision						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Endocrine disorders						
Yes	4 (0.8)	4	0.6	0		
No	10 (1.2)	12	1.2	6 (1.4)	7	1.3
Thyroid gland disorders						
Yes	4 (0.8)	4	0.6	0		
No	9 (1.1)	11	1.1	6 (1.4)	6	1.1
Hypothyroidism						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	4 (0.9)	4	0.7
Goitre						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	2	0.2	0		
Hyperthyroidism						
Yes	1 (0.2)	1	0.1	0		
No	2 (0.2)	3	0.3	0		
Thyroid mass						
Yes	0			0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Thyroid cyst						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Primary hyperthyroidism						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Adrenal gland disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hyperadrenocorticism						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Endocrine disorders of gonadal function						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Hypogonadism						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Social circumstances						
Yes	1	(0.2)	1 0.1	1	(0.4)	1 0.3
No	5	(0.6)	5 0.5	0		
Age related factors						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Menopause						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Economic and housing issues						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Stress at work						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Family issues						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Family stress						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Lifestyle issues						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Bedridden						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Congenital, familial and genetic disorders						
Yes	2	(0.4)	2 0.3	1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Metabolic and nutritional disorders congenital						
Yes	1	(0.2)	1 0.1	0		
No	2	(0.2)	2 0.2	0		
Type V hyperlipidaemia						
Yes	1	(0.2)	1 0.1	0		
No	1	(0.1)	1 <0.1	0		
Gilbert's syndrome						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue disorders congenital						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Carpus curvus						
Yes	1 (0.2)	1	0.1	0		
No	0			0		
Skin and subcutaneous tissue disorders congenital						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Dermoid cyst						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Pregnancy, puerperium and perinatal conditions						
Yes	0			0		
No	5 (0.6)	5	0.5	0		
Abortions and stillbirth						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Abortion spontaneous						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Abortion						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	1	(0.1)	1 <0.1	0		
Maternal complications of pregnancy						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Ectopic pregnancy						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Morning sickness						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Product issues						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Device issues						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Device expulsion						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

33 Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Yes	276	364.6			265	348.1			284	375.0		
No	126	165.1			138	185.0			118	153.3		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Yes	233	(84.4)	1331	365.0	238	(89.8)	1531	439.9	225	(79.2)	1034	275.7
No	96	(76.2)	528	319.7	115	(83.3)	666	360.0	84	(71.2)	354	230.9
Serious												
Yes												
Yes	23	(8.3)	40	11.0	28	(10.6)	58	16.7	33	(11.6)	48	12.8
No	8	(6.3)	13	7.9	12	(8.7)	13	7.0	4	(3.4)	5	3.3
No												
Yes	230	(83.3)	1291	354.1	238	(89.8)	1473	423.2	223	(78.5)	986	262.9
No	96	(76.2)	515	311.8	114	(82.6)	653	353.0	84	(71.2)	349	227.7
Severity												
Severe												
Yes	17	(6.2)	37	10.1	20	(7.5)	41	11.8	22	(7.7)	31	8.3
No	5	(4.0)	6	3.6	7	(5.1)	10	5.4	6	(5.1)	8	5.2
Moderate												
Yes	93	(33.7)	231	63.4	118	(44.5)	336	96.5	94	(33.1)	219	58.4
No	42	(33.3)	84	50.9	55	(39.9)	172	93.0	24	(20.3)	45	29.4
Mild												
Yes	216	(78.3)	1063	291.5	220	(83.0)	1154	331.5	202	(71.1)	784	209.0
No	90	(71.4)	438	265.2	108	(78.3)	484	261.7	77	(65.3)	301	196.4

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Missing									
Yes	9 (3.3)	10	2.7	7 (2.6)	7	2.0	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	3 (2.2)	3	1.6	2 (1.7)	3	2.0
Probable									
Yes	97 (35.1)	226	62.0	117 (44.2)	306	87.9	43 (15.1)	68	18.1
No	36 (28.6)	118	71.5	52 (37.7)	150	81.1	19 (16.1)	32	20.9
Possible									
Yes	110 (39.9)	291	79.8	120 (45.3)	343	98.5	66 (23.2)	120	32.0
No	43 (34.1)	116	70.2	62 (44.9)	191	103.3	27 (22.9)	50	32.6
Unlikely									
Yes	210 (76.1)	804	220.5	207 (78.1)	875	251.4	213 (75.0)	842	224.5
No	86 (68.3)	293	177.4	94 (68.1)	322	174.1	76 (64.4)	269	175.5
Outcome									
Fatal									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Recovered									
Yes	224 (81.2)	1053	288.8	227 (85.7)	1256	360.9	209 (73.6)	785	209.3
No	91 (72.2)	450	272.5	106 (76.8)	556	300.6	76 (64.4)	269	175.5
Recovering									
Yes	18 (6.5)	31	8.5	12 (4.5)	20	5.7	15 (5.3)	17	4.5
No	1 (0.8)	1	0.6	5 (3.6)	6	3.2	2 (1.7)	2	1.3
Recovered With Sequelae									
Yes	5 (1.8)	5	1.4	3 (1.1)	3	0.9	1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	0		
Not Recovered									
Yes	109 (39.5)	242	66.4	110 (41.5)	245	70.4	115 (40.5)	228	60.8

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Outcome									
Not Recovered									
No	38 (30.2)	77	46.6	53 (38.4)	100	54.1	41 (34.7)	82	53.5
Unknown									
Yes	0			3 (1.1)	7	2.0	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Leading to									
Permanent treatment discontinuation									
Yes	15 (5.4)	18	4.9	23 (8.7)	32	9.2	10 (3.5)	12	3.2
No	5 (4.0)	5	3.0	2 (1.4)	2	1.1	4 (3.4)	6	3.9
Temporary interruption of trial product									
Yes	16 (5.8)	28	7.7	21 (7.9)	57	16.4	10 (3.5)	15	4.0
No	10 (7.9)	19	11.5	16 (11.6)	33	17.8	5 (4.2)	5	3.3
Dose reduction of trial product									
Yes	12 (4.3)	16	4.4	22 (8.3)	38	10.9	2 (0.7)	2	0.5
No	6 (4.8)	12	7.3	13 (9.4)	28	15.1	1 (0.8)	1	0.7

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

34 Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Yes	276		364.6		265		348.1		284		375.0	
No	126		165.1		138		185.0		118		153.3	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Yes	233	(84.4)	1331	365.0	238	(89.8)	1531	439.9	225	(79.2)	1034	275.7
No	96	(76.2)	528	319.7	115	(83.3)	666	360.0	84	(71.2)	354	230.9
Gastrointestinal disorders												
Yes	165	(59.8)	502	137.7	175	(66.0)	602	173.0	98	(34.5)	187	49.9
No	66	(52.4)	222	134.4	81	(58.7)	322	174.1	40	(33.9)	75	48.9
Gastrointestinal signs and symptoms												
Yes	137	(49.6)	291	79.8	141	(53.2)	408	117.2	54	(19.0)	85	22.7
No	50	(39.7)	141	85.4	59	(42.8)	193	104.3	22	(18.6)	30	19.6
Nausea												
Yes	96	(34.8)	139	38.1	90	(34.0)	159	45.7	28	(9.9)	36	9.6
No	33	(26.2)	59	35.7	46	(33.3)	90	48.7	9	(7.6)	9	5.9
Vomiting												
Yes	33	(12.0)	58	15.9	59	(22.3)	140	40.2	9	(3.2)	9	2.4
No	21	(16.7)	35	21.2	29	(21.0)	48	25.9	2	(1.7)	3	2.0
Abdominal distension												
Yes	6	(2.2)	6	1.6	16	(6.0)	19	5.5	5	(1.8)	7	1.9
No	3	(2.4)	6	3.6	8	(5.8)	11	5.9	6	(5.1)	6	3.9
Dyspepsia												
Yes	21	(7.6)	21	5.8	20	(7.5)	25	7.2	3	(1.1)	3	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	6 (4.8)	6	3.6	5 (3.6)	5	2.7	2 (1.7)	2	1.3
Abdominal pain upper									
Yes	8 (2.9)	8	2.2	8 (3.0)	11	3.2	6 (2.1)	7	1.9
No	3 (2.4)	3	1.8	8 (5.8)	10	5.4	5 (4.2)	6	3.9
Eructation									
Yes	7 (2.5)	8	2.2	9 (3.4)	11	3.2	1 (0.4)	1	0.3
No	4 (3.2)	8	4.8	7 (5.1)	10	5.4	0		
Flatulence									
Yes	13 (4.7)	15	4.1	11 (4.2)	14	4.0	6 (2.1)	8	2.1
No	8 (6.3)	10	6.1	5 (3.6)	7	3.8	1 (0.8)	1	0.7
Abdominal discomfort									
Yes	10 (3.6)	12	3.3	9 (3.4)	11	3.2	5 (1.8)	5	1.3
No	5 (4.0)	5	3.0	4 (2.9)	4	2.2	2 (1.7)	2	1.3
Abdominal pain									
Yes	11 (4.0)	12	3.3	9 (3.4)	11	3.2	4 (1.4)	4	1.1
No	6 (4.8)	8	4.8	4 (2.9)	4	2.2	1 (0.8)	1	0.7
Abdominal pain lower									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	0			2 (1.4)	2	1.1	0		
Regurgitation									
Yes	0			2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Aerophagia									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Abnormal faeces									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Epigastric discomfort									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Gastrointestinal pain									
Yes	1	(0.4)	1 0.3	1	(0.4)	1 0.3	0		
No	0			0			0		
Gastrointestinal sounds abnormal									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Abdominal rigidity									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Anal incontinence									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Breath odour									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Dysphagia									
Yes	2	(0.7)	2 0.5	0			0		
No	0			0			0		
Faeces discoloured									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Faeces soft									
Yes	1	(0.4)	1 0.3	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	0			0		
Retching									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal motility and defaecation conditions									
Yes	89 (32.2)	175	48.0	92 (34.7)	138	39.6	50 (17.6)	70	18.7
No	36 (28.6)	68	41.2	51 (37.0)	101	54.6	20 (16.9)	31	20.2
Diarrhoea									
Yes	61 (22.1)	113	31.0	47 (17.7)	70	20.1	36 (12.7)	47	12.5
No	28 (22.2)	45	27.2	39 (28.3)	71	38.4	12 (10.2)	19	12.4
Constipation									
Yes	39 (14.1)	52	14.3	50 (18.9)	56	16.1	15 (5.3)	19	5.1
No	12 (9.5)	18	10.9	20 (14.5)	26	14.1	7 (5.9)	7	4.6
Gastrooesophageal reflux disease									
Yes	9 (3.3)	9	2.5	10 (3.8)	10	2.9	3 (1.1)	3	0.8
No	4 (3.2)	5	3.0	2 (1.4)	3	1.6	4 (3.4)	4	2.6
Change of bowel habit									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Gastrointestinal motility disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Irritable bowel syndrome									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal hypermotility									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Gastrooesophageal sphincter insufficiency									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal conditions NEC									
Yes	4 (1.4)	4	1.1	10 (3.8)	13	3.7	4 (1.4)	4	1.1
No	3 (2.4)	4	2.4	8 (5.8)	8	4.3	2 (1.7)	2	1.3
Hyperchlorhydria									
Yes	3 (1.1)	3	0.8	4 (1.5)	7	2.0	1 (0.4)	1	0.3
No	2 (1.6)	3	1.8	7 (5.1)	7	3.8	1 (0.8)	1	0.7
Food poisoning									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Gastrointestinal disorder									
Yes	0			3 (1.1)	3	0.9	0		
No	0			0			0		
Barrett's oesophagus									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Gastric disorder									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Gastrointestinal melanosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions									
Yes	5 (1.8)	5	1.4	10 (3.8)	12	3.4	3 (1.1)	3	0.8
No	4 (3.2)	4	2.4	7 (5.1)	8	4.3	3 (2.5)	5	3.3
Gastritis									
Yes	4 (1.4)	4	1.1	7 (2.6)	8	2.3	2 (0.7)	2	0.5
No	2 (1.6)	2	1.2	4 (2.9)	5	2.7	2 (1.7)	4	2.6
Enteritis									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	0		
Enterocolitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Chronic gastritis									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Duodenitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Colitis									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			0		
Gastrointestinal vascular conditions									
Yes	3 (1.1)	5	1.4	6 (2.3)	6	1.7	2 (0.7)	2	0.5
No	0			3 (2.2)	3	1.6	0		
Haemorrhoids									
Yes	2 (0.7)	3	0.8	6 (2.3)	6	1.7	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			3 (2.2)	3	1.6	0		
Haemorrhoids thrombosed									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Varices oesophageal									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Dental and gingival conditions									
Yes	4 (1.4)	4	1.1	10 (3.8)	11	3.2	7 (2.5)	7	1.9
No	4 (3.2)	5	3.0	0			0		
Toothache									
Yes	2 (0.7)	2	0.5	5 (1.9)	5	1.4	2 (0.7)	2	0.5
No	2 (1.6)	3	1.8	0			0		
Dental caries									
Yes	0			4 (1.5)	4	1.1	5 (1.8)	5	1.3
No	2 (1.6)	2	1.2	0			0		
Gingival swelling									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Tooth deposit									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Periodontal disease									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Salivary gland conditions									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			3 (2.2)	4	2.2	1 (0.8)	1	0.7
Dry mouth									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Parotid gland enlargement									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Salivary hypersecretion									
Yes	0			0			0		
No	0			1 (0.7)	2	1.1	0		
Noninfective sialoadenitis									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Abdominal hernias and other abdominal wall conditions									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	3 (1.1)	3	0.8
No	0			1 (0.7)	1	0.5	2 (1.7)	2	1.3
Abdominal wall haematoma									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Abdominal hernia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hiatus hernia									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Umbilical hernia									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Inguinal hernia									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Gastrointestinal haemorrhages NEC									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Haematochezia									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	0		
No	0			0			0		
Intra-abdominal haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Mallory-Weiss syndrome									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Upper gastrointestinal haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Intra-abdominal haematoma									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Rectal haemorrhage									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Benign neoplasms gastrointestinal									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	5 (1.8)	6	1.6	2 (0.8)	2	0.6	3 (1.1)	3	0.8
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Gastric polyps									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Large intestine polyp									
Yes	4 (1.4)	4	1.1	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Oral soft tissue conditions									
Yes	0			1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Stomatitis									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Mouth ulceration									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Aphthous ulcer									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Lip swelling									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Odynophagia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Anal and rectal conditions NEC									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Anal fissure									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Gastrointestinal stenosis and obstruction									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Small intestinal obstruction									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Diverticular disorders									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	0			0			0		
Diverticulum intestinal									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Diverticulum									
Yes	1 (0.4)	1	0.3	0			3 (1.1)	3	0.8
No	0			0			0		
Exocrine pancreas conditions									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Pancreatitis acute									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Obstructive pancreatitis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Pancreatic cyst									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal ulceration and perforation									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Gastritis erosive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diverticular perforation									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Gastric ulcer									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Malabsorption conditions									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Malabsorption									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Peritoneal and retroperitoneal conditions									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Retroperitoneal mass									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tongue conditions									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Glossodynia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Infections and infestations									
Yes	124 (44.9)	241	66.1	133 (50.2)	257	73.8	133 (46.8)	281	74.9
No	42 (33.3)	77	46.6	46 (33.3)	88	47.6	42 (35.6)	78	50.9
Infections - pathogen unspecified									
Yes	112 (40.6)	191	52.4	119 (44.9)	213	61.2	113 (39.8)	218	58.1
No	34 (27.0)	59	35.7	43 (31.2)	76	41.1	34 (28.8)	63	41.1
Nasopharyngitis									
Yes	38 (13.8)	58	15.9	50 (18.9)	81	23.3	46 (16.2)	70	18.7
No	9 (7.1)	11	6.7	18 (13.0)	34	18.4	13 (11.0)	22	14.4
Upper respiratory tract infection									
Yes	29 (10.5)	38	10.4	32 (12.1)	37	10.6	29 (10.2)	38	10.1
No	8 (6.3)	16	9.7	10 (7.2)	11	5.9	9 (7.6)	12	7.8
Bronchitis									
Yes	9 (3.3)	10	2.7	8 (3.0)	9	2.6	10 (3.5)	12	3.2
No	1 (0.8)	1	0.6	6 (4.3)	7	3.8	3 (2.5)	3	2.0

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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastroenteritis									
Yes	18 (6.5)	22	6.0	10 (3.8)	11	3.2	8 (2.8)	10	2.7
No	6 (4.8)	6	3.6	4 (2.9)	4	2.2	5 (4.2)	5	3.3
Sinusitis									
Yes	5 (1.8)	5	1.4	10 (3.8)	15	4.3	11 (3.9)	13	3.5
No	1 (0.8)	1	0.6	4 (2.9)	4	2.2	0		
Urinary tract infection									
Yes	13 (4.7)	15	4.1	9 (3.4)	12	3.4	10 (3.5)	13	3.5
No	4 (3.2)	6	3.6	4 (2.9)	4	2.2	2 (1.7)	3	2.0
Conjunctivitis									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	4 (1.4)	5	1.3
No	1 (0.8)	3	1.8	2 (1.4)	2	1.1	0		
Lower respiratory tract infection									
Yes	1 (0.4)	1	0.3	0			3 (1.1)	3	0.8
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	3 (2.5)	3	2.0
Pharyngitis									
Yes	0			0			5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	3 (2.2)	3	1.6	2 (1.7)	2	1.3
Paronychia									
Yes	0			3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	0		
Pneumonia									
Yes	1 (0.4)	1	0.3	3 (1.1)	4	1.1	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Cystitis									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	1 (0.4)	2	0.5
No	0			0			2 (1.7)	3	2.0

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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tonsillitis									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	3 (1.1)	3	0.8
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Gastrointestinal infection									
Yes	0			2 (0.8)	3	0.9	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Acute sinusitis									
Yes	4 (1.4)	4	1.1	2 (0.8)	2	0.6	3 (1.1)	5	1.3
No	0			0			0		
Localised infection									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	0		
No	0			0			0		
Otitis externa									
Yes	4 (1.4)	4	1.1	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Tooth infection									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	2	1.2	0			0		
Breast abscess									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Abscess									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Appendicitis									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Chronic sinusitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diverticulitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Implant site infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Infected dermal cyst									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Kidney infection									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Mastitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Otitis media acute									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Periodontitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	2	1.3
Post procedural infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Respiratory tract infection									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	0			0			2 (1.7)	2	1.3
Rhinitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	0			0			0		
Skin infection									
Yes	0			1 (0.4)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Tooth abscess									
Yes	4 (1.4)	4	1.1	1 (0.4)	1	0.3	1 (0.4)	2	0.5
No	0			0			0		
Urosepsis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vulvovaginitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	2	0.6	0		
No	0			0			0		
Colonic abscess									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Ear infection									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Empyema									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Eye infection									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Gingival abscess									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Gingivitis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			2 (1.7)	2	1.3
Hordeolum									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Joint abscess									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Labyrinthitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Laryngitis									
Yes	3 (1.1)	4	1.1	0			0		
No	0			0			0		
Mastoiditis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Osteomyelitis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Otitis media									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Otitis media chronic									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Pericoronitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Postoperative wound infection									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Pulpitis dental									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Pyelonephritis acute									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Sepsis									
Yes	3 (1.1)	3	0.8	0			0		
No	0			0			0		
Sialoadenitis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Sinobronchitis									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Subcutaneous abscess									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Tracheitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tracheobronchitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Vaginal infection									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Wound infection									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Viral infectious disorders									
Yes	26 (9.4)	30	8.2	26 (9.8)	30	8.6	31 (10.9)	34	9.1
No	9 (7.1)	11	6.7	10 (7.2)	11	5.9	5 (4.2)	8	5.2
Influenza									
Yes	13 (4.7)	15	4.1	12 (4.5)	12	3.4	14 (4.9)	15	4.0
No	4 (3.2)	4	2.4	3 (2.2)	4	2.2	4 (3.4)	7	4.6
Gastroenteritis viral									
Yes	4 (1.4)	4	1.1	4 (1.5)	5	1.4	7 (2.5)	7	1.9
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	0		
Viral infection									
Yes	2 (0.7)	2	0.5	3 (1.1)	4	1.1	3 (1.1)	4	1.1
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Herpes zoster									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Herpes simplex									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Pneumonia influenzal									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Respiratory tract infection viral									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Viral pharyngitis									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Gastroenteritis norovirus									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Herpes virus infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ophthalmic herpes zoster									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Oral herpes									
Yes	2 (0.7)	3	0.8	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Viral diarrhoea									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Chikungunya virus infection									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Ear infection viral									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Rhinovirus infection									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Viral upper respiratory tract infection									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	2 (1.6)	3	1.8	0			0		
Bacterial infectious disorders									
Yes	8 (2.9)	11	3.0	7 (2.6)	7	2.0	9 (3.2)	14	3.7
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	3 (2.5)	4	2.6
Cellulitis									
Yes	5 (1.8)	6	1.6	1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Bacterial vaginosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Breast cellulitis									
Yes	0			1 (0.4)	1	0.3	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Ear infection bacterial									
Yes	1 (0.4)	3	0.8	1 (0.4)	1	0.3	0		
No	0			0			0		
Furuncle									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Pharyngitis streptococcal									
Yes	0			1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	1 (0.8)	1	0.6	0			0		
Staphylococcal infection									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	2	1.3
Clostridium difficile colitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Helicobacter gastritis									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Helicobacter infection									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Wound infection staphylococcal									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Fungal infectious disorders									
Yes	9 (3.3)	9	2.5	7 (2.6)	7	2.0	13 (4.6)	15	4.0

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	5 (4.0)	5	3.0	0			2 (1.7)	2	1.3
Onychomycosis									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Fungal infection									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			0		
Fungal skin infection									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Tinea pedis									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Vulvovaginal candidiasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	0			0			0		
Vulvovaginal mycotic infection									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	0			0			0		
Balanitis candida									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Candida infection									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Dermatophytosis of nail									
Yes	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Genital candidiasis									
Yes	1	(0.4)	1 0.3	0			0		
No	1	(0.8)	1 0.6	0			0		
Genital infection fungal									
Yes	0			0			0		
No	1	(0.8)	1 0.6	0			0		
Skin candida									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Tinea infection									
Yes	0			0			2	(0.7)	2 0.5
No	1	(0.8)	1 0.6	0			0		
Tinea versicolour									
Yes	2	(0.7)	2 0.5	0			0		
No	0			0			0		
Ectoparasitic disorders									
Yes	0			0			0		
No	0			0			1	(0.8)	1 0.7
Acarodermatitis									
Yes	0			0			0		
No	0			0			1	(0.8)	1 0.7
Musculoskeletal and connective tissue disorders									
Yes	73	(26.4)	111 30.4	71	(26.8)	117 33.6	63	(22.2)	97 25.9
No	26	(20.6)	36 21.8	27	(19.6)	34 18.4	21	(17.8)	29 18.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue disorders NEC									
Yes	38 (13.8)	44	12.1	39 (14.7)	48	13.8	24 (8.5)	28	7.5
No	19 (15.1)	22	13.3	17 (12.3)	18	9.7	9 (7.6)	10	6.5
Back pain									
Yes	19 (6.9)	21	5.8	23 (8.7)	26	7.5	12 (4.2)	13	3.5
No	9 (7.1)	9	5.4	4 (2.9)	4	2.2	2 (1.7)	2	1.3
Pain in extremity									
Yes	7 (2.5)	7	1.9	11 (4.2)	11	3.2	6 (2.1)	6	1.6
No	5 (4.0)	5	3.0	5 (3.6)	5	2.7	4 (3.4)	4	2.6
Neck pain									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	4 (2.9)	4	2.2	1 (0.8)	1	0.7
Musculoskeletal pain									
Yes	4 (1.4)	4	1.1	5 (1.9)	5	1.4	4 (1.4)	4	1.1
No	4 (3.2)	4	2.4	2 (1.4)	2	1.1	2 (1.7)	2	1.3
Flank pain									
Yes	2 (0.7)	2	0.5	0			0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Musculoskeletal chest pain									
Yes	3 (1.1)	4	1.1	0			1 (0.4)	1	0.3
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	0		
Rheumatic disorder									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Muscle contracture									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Neck mass									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Axillary mass									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Limb mass									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Musculoskeletal discomfort									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Musculoskeletal stiffness									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Plantar fasciitis									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Joint disorders									
Yes	30 (10.9)	36	9.9	34 (12.8)	45	12.9	29 (10.2)	36	9.6
No	8 (6.3)	10	6.1	10 (7.2)	12	6.5	12 (10.2)	13	8.5
Arthralgia									
Yes	18 (6.5)	20	5.5	19 (7.2)	25	7.2	14 (4.9)	14	3.7
No	6 (4.8)	7	4.2	4 (2.9)	4	2.2	6 (5.1)	6	3.9
Osteoarthritis									
Yes	1 (0.4)	1	0.3	7 (2.6)	9	2.6	8 (2.8)	9	2.4

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	4 (2.9)	5	2.7	4 (3.4)	4	2.6
Periarthritis									
Yes	2 (0.7)	2	0.5	2 (0.8)	3	0.9	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	2	1.1	0		
Rotator cuff syndrome									
Yes	5 (1.8)	7	1.9	3 (1.1)	4	1.1	0		
No	0			0			0		
Arthritis									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Spinal osteoarthritis									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Joint swelling									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Arthritis climacteric									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Arthropathy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Femoroacetabular impingement									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Gouty arthritis									
Yes	0			0			1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Joint effusion									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Neuropathic arthropathy									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Psoriatic arthropathy									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Rheumatoid arthritis									
Yes	0			0			1 (0.4)	2	0.5
No	0			0			0		
Sacroiliitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Muscle disorders									
Yes	11 (4.0)	15	4.1	8 (3.0)	10	2.9	6 (2.1)	7	1.9
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	2 (1.7)	2	1.3
Muscle spasms									
Yes	7 (2.5)	8	2.2	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Myalgia									
Yes	5 (1.8)	7	1.9	4 (1.5)	6	1.7	3 (1.1)	4	1.1
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Diastasis recti abdominis									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (0.8)	1	0.7
Muscular weakness									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Tendon, ligament and cartilage disorders									
Yes	4 (1.4)	4	1.1	5 (1.9)	5	1.4	7 (2.5)	8	2.1
No	2 (1.6)	2	1.2	0			2 (1.7)	2	1.3
Trigger finger									
Yes	0			2 (0.8)	2	0.6	2 (0.7)	2	0.5
No	0			0			0		
Osteochondrosis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Tendon disorder									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Tendonitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	0			0			2 (1.7)	2	1.3
Costochondritis									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Ligament calcification									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Meniscal degeneration									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tendon pain									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Synovial and bursal disorders									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	5 (1.8)	6	1.6
No	0			1 (0.7)	1	0.5	0		
Bursitis									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	5 (1.8)	6	1.6
No	0			1 (0.7)	1	0.5	0		
Bone disorders (excl congenital and fractures)									
Yes	6 (2.2)	6	1.6	2 (0.8)	3	0.9	4 (1.4)	4	1.1
No	0			1 (0.7)	1	0.5	0		
Exostosis									
Yes	3 (1.1)	3	0.8	0			2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Bone lesion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Osteopenia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Osteoporosis									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bone pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Metatarsalgia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Osteitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Yes	4 (1.4)	4	1.1	3 (1.1)	3	0.9	7 (2.5)	8	2.1
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Intervertebral disc protrusion									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	3 (1.1)	3	0.8
No	0			0			0		
Foot deformity									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	2	0.5
No	0			0			0		
Intervertebral disc degeneration									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Scoliosis									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			0		
Spinal flattening									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Spondylolisthesis									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Connective tissue disorders (excl congenital)									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Polymyalgia rheumatica									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Nervous system disorders									
Yes	37 (13.4)	69	18.9	63 (23.8)	94	27.0	48 (16.9)	67	17.9
No	26 (20.6)	36	21.8	19 (13.8)	24	13.0	15 (12.7)	25	16.3
Headaches									
Yes	21 (7.6)	38	10.4	26 (9.8)	34	9.8	18 (6.3)	20	5.3
No	15 (11.9)	18	10.9	11 (8.0)	12	6.5	6 (5.1)	12	7.8
Headache									
Yes	19 (6.9)	32	8.8	21 (7.9)	29	8.3	14 (4.9)	15	4.0
No	14 (11.1)	16	9.7	10 (7.2)	11	5.9	6 (5.1)	12	7.8
Migraine									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	0		
No	1 (0.8)	1	0.6	0			0		
Migraine with aura									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	0		
Tension headache									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Occipital neuralgia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Sinus headache									
Yes	1 (0.4)	2	0.5	0			1 (0.4)	1	0.3
No	0			0			0		
Neurological disorders NEC									
Yes	18 (6.5)	22	6.0	28 (10.6)	36	10.3	23 (8.1)	29	7.7
No	10 (7.9)	11	6.7	8 (5.8)	10	5.4	8 (6.8)	9	5.9
Dizziness									
Yes	12 (4.3)	15	4.1	13 (4.9)	13	3.7	12 (4.2)	14	3.7
No	6 (4.8)	6	3.6	6 (4.3)	7	3.8	1 (0.8)	1	0.7
Paraesthesia									
Yes	0			4 (1.5)	6	1.7	3 (1.1)	3	0.8
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	3 (2.5)	4	2.6
Dysgeusia									
Yes	0			4 (1.5)	8	2.3	1 (0.4)	1	0.3
No	0			0			0		
Hypoaesthesia									
Yes	0			3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	0			0			0		
Somnolence									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	0		
Syncope									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Dizziness postural									
Yes	0			2 (0.8)	2	0.6	0		
No	1 (0.8)	2	1.2	0			0		
Hyperaesthesia									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	0		
No	0			0			0		
Ageusia									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Aphasia									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Coordination abnormal									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Dysaesthesia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Head discomfort									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hypogeusia									
Yes	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Lethargy									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Loss of consciousness									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Neuralgia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Phantom limb syndrome									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Presyncope									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Restless legs syndrome									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Central nervous system vascular disorders									
Yes	1 (0.4)	1	0.3	7 (2.6)	10	2.9	2 (0.7)	3	0.8
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Carotid arteriosclerosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Carotid artery stenosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	0		
No	0			0			0		
Cerebrovascular accident									
Yes	0			2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Cerebral artery stenosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cerebral artery thrombosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cerebral infarction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Spinal epidural haematoma									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Subarachnoid haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ischaemic stroke									
Yes	0			0			1 (0.4)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Peripheral neuropathies									
Yes	5 (1.8)	6	1.6	4 (1.5)	4	1.1	5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	0			2 (1.7)	3	2.0
Carpal tunnel syndrome									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (1.1)	4	1.1	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Diabetic neuropathy									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Meralgia paraesthetica									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Neuropathy peripheral									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	2	1.3
Nerve compression									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Polyneuropathy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Spinal cord and nerve root disorders									
Yes	2 (0.7)	2	0.5	2 (0.8)	3	0.9	4 (1.4)	4	1.1
No	3 (2.4)	3	1.8	1 (0.7)	1	0.5	0		
Sciatica									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Radiculopathy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Sacral radiculopathy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Cervical radiculopathy									
Yes	0			0			0		
No	1	(0.8)	1 0.6	0			0		
Cervicobrachial syndrome									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Lumbar radiculopathy									
Yes	0			0			2	(0.7)	2 0.5
No	1	(0.8)	1 0.6	0			0		
Cranial nerve disorders (excl neoplasms)									
Yes	0			2	(0.8)	2 0.6	0		
No	0			0			0		
Anosmia									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Facial paralysis									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Encephalopathies									
Yes	0			2	(0.8)	2 0.6	0		
No	0			0			0		
Hepatic encephalopathy									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Hyponatraemic encephalopathy												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Mental impairment disorders												
Yes	0				1	(0.4)	1	0.3	3	(1.1)	3	0.8
No	1	(0.8)	1	0.6	0				1	(0.8)	1	0.7
Memory impairment												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Amnesia												
Yes	0				0				2	(0.7)	2	0.5
No	0				0				1	(0.8)	1	0.7
Dementia Alzheimer's type												
Yes	0				0				1	(0.4)	1	0.3
No	0				0				0			
Vascular dementia												
Yes	0				0				0			
No	1	(0.8)	1	0.6	0				0			
Sleep disturbances (incl subtypes)												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Hypersomnia												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Structural brain disorders												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cerebral ventricle dilatation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Movement disorders (incl parkinsonism)									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Tremor									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Neurological disorders of the eye									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Visual field defect									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Seizures (incl subtypes)									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Partial seizures									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
General disorders and administration site conditions									
Yes	40 (14.5)	54	14.8	49 (18.5)	65	18.7	33 (11.6)	43	11.5
No	11 (8.7)	15	9.1	20 (14.5)	28	15.1	13 (11.0)	18	11.7
General system disorders NEC									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	32 (11.6)	40	11.0	41 (15.5)	49	14.1	21 (7.4)	22	5.9
No	8 (6.3)	12	7.3	16 (11.6)	19	10.3	7 (5.9)	8	5.2
Fatigue									
Yes	17 (6.2)	20	5.5	22 (8.3)	22	6.3	3 (1.1)	3	0.8
No	2 (1.6)	6	3.6	6 (4.3)	7	3.8	1 (0.8)	1	0.7
Asthenia									
Yes	3 (1.1)	3	0.8	4 (1.5)	5	1.4	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	3 (2.2)	3	1.6	0		
Influenza like illness									
Yes	0			3 (1.1)	4	1.1	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	2 (1.7)	2	1.3
Non-cardiac chest pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			3 (2.2)	3	1.6	0		
Early satiety									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Malaise									
Yes	1 (0.4)	2	0.5	3 (1.1)	3	0.9	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Pain									
Yes	4 (1.4)	4	1.1	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	2 (1.7)	2	1.3
Peripheral swelling									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	2 (1.7)	2	1.3
Oedema peripheral									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	3 (1.1)	3	0.8
No	0			0			1 (0.8)	1	0.7
Chest discomfort									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Chest pain									
Yes	0			1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	1 (0.8)	1	0.6	0			0		
Face oedema									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Feeling cold									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hunger									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Swelling									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thirst decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Chills									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Discomfort									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Inflammation									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Polyp									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Sensation of foreign body									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Thirst									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Administration site reactions									
Yes	5 (1.8)	6	1.6	10 (3.8)	12	3.4	8 (2.8)	14	3.7
No	1 (0.8)	1	0.6	3 (2.2)	7	3.8	2 (1.7)	4	2.6
Injection site pain									
Yes	3 (1.1)	3	0.8	5 (1.9)	7	2.0	2 (0.7)	6	1.6
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	1 (0.8)	1	0.7
Injection site erythema									
Yes	0			2 (0.8)	2	0.6	0		
No	0			1 (0.7)	1	0.5	0		
Injection site reaction									
Yes	0			0			0		
No	0			2 (1.4)	2	1.1	0		
Injection site bruising									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (1.1)	3	0.8	2 (0.8)	2	0.6	4 (1.4)	4	1.1
No	0			0			1 (0.8)	2	1.3
Injection site mass									
Yes	0			0			0		
No	0			1 (0.7)	2	1.1	1 (0.8)	1	0.7
Implant site pain									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Injection site discomfort									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Injection site haemorrhage									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Injection site urticaria									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Body temperature conditions									
Yes	7 (2.5)	7	1.9	3 (1.1)	3	0.9	4 (1.4)	6	1.6
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	5 (4.2)	6	3.9
Pyrexia									
Yes	7 (2.5)	7	1.9	3 (1.1)	3	0.9	4 (1.4)	6	1.6
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	5 (4.2)	6	3.9
Tissue disorders NEC									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Mass									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Nodule									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Therapeutic and nontherapeutic effects (excl toxicity)									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Drug intolerance									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Complications associated with device									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Complication associated with device									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Metabolism and nutrition disorders									
Yes	39 (14.1)	57	15.6	36 (13.6)	40	11.5	37 (13.0)	44	11.7
No	9 (7.1)	11	6.7	20 (14.5)	26	14.1	16 (13.6)	17	11.1
Appetite and general nutritional disorders									
Yes	25 (9.1)	32	8.8	27 (10.2)	28	8.0	14 (4.9)	16	4.3
No	7 (5.6)	8	4.8	14 (10.1)	18	9.7	2 (1.7)	2	1.3
Decreased appetite									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	23 (8.3)	27	7.4	26 (9.8)	27	7.8	13 (4.6)	15	4.0
No	6 (4.8)	7	4.2	12 (8.7)	14	7.6	2 (1.7)	2	1.3
Hyperphagia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Increased appetite									
Yes	4 (1.4)	5	1.4	0			0		
No	0			1 (0.7)	1	0.5	0		
Overweight									
Yes	0			0			0		
No	0			1 (0.7)	2	1.1	0		
Cachexia									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Obesity									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Lipid metabolism disorders									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	1 (0.8)	1	0.6	4 (2.9)	4	2.2	6 (5.1)	6	3.9
Dyslipidaemia									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	3 (2.2)	3	1.6	4 (3.4)	4	2.6
Hyperlipidaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Hypertriglyceridaemia									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Hypercholesterolaemia									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Electrolyte and fluid balance conditions									
Yes	6 (2.2)	7	1.9	7 (2.6)	7	2.0	3 (1.1)	3	0.8
No	0			0			0		
Dehydration									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	0			0			0		
Hypokalaemia									
Yes	2 (0.7)	3	0.8	3 (1.1)	3	0.9	0		
No	0			0			0		
Hyponatraemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Hyperkalaemia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Purine and pyrimidine metabolism disorders									
Yes	3 (1.1)	4	1.1	0			2 (0.7)	3	0.8
No	0			2 (1.4)	2	1.1	1 (0.8)	2	1.3
Gout									
Yes	3 (1.1)	4	1.1	0			1 (0.4)	2	0.5

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			2 (1.4)	2	1.1	1 (0.8)	2	1.3
Hyperuricaemia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Vitamin related disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Folate deficiency									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Vitamin B complex deficiency									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Vitamin D deficiency									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Glucose metabolism disorders (incl diabetes mellitus)									
Yes	1 (0.4)	2	0.5	0			14 (4.9)	14	3.7
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	6 (5.1)	6	3.9
Diabetes mellitus									
Yes	0			0			6 (2.1)	6	1.6
No	0			1 (0.7)	1	0.5	0		
Diabetes mellitus inadequate control									
Yes	1 (0.4)	2	0.5	0			2 (0.7)	2	0.5
No	0			0			3 (2.5)	3	2.0
Hyperglycaemia									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Hyperinsulinaemia									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Hypoglycaemia									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Type 2 diabetes mellitus									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Acid-base disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Ketoacidosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Lactic acidosis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Bone, calcium, magnesium and phosphorus metabolism disorders									
Yes	4 (1.4)	4	1.1	1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	0			0			0		
Hypomagnesaemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hypercalcaemia									
Yes	2 (0.7)	2	0.5	0			2 (0.7)	2	0.5
No	0			0			0		
Hypercalcitoninaemia									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Hypocalcaemia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Diabetic complications									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Diabetic ketoacidosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diabetic metabolic decompensation									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Iron and trace metal metabolism disorders									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Iron deficiency									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Metabolism disorders NEC									
Yes	1 (0.4)	2	0.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Hyperamylasaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hyperlipasaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Eye disorders									
Yes	31 (11.2)	42	11.5	31 (11.7)	48	13.8	31 (10.9)	42	11.2
No	15 (11.9)	23	13.9	19 (13.8)	21	11.4	11 (9.3)	14	9.1
Retina, choroid and vitreous haemorrhages and vascular disorders									
Yes	7 (2.5)	8	2.2	13 (4.9)	15	4.3	6 (2.1)	6	1.6
No	5 (4.0)	5	3.0	8 (5.8)	8	4.3	5 (4.2)	6	3.9
Diabetic retinopathy									
Yes	7 (2.5)	8	2.2	10 (3.8)	11	3.2	6 (2.1)	6	1.6
No	4 (3.2)	4	2.4	5 (3.6)	5	2.7	5 (4.2)	6	3.9
Non-proliferative retinopathy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Retinopathy hypertensive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Retinal haemorrhage									
Yes	0			2 (0.8)	2	0.6	0		
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retinal artery occlusion									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Retinopathy									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Anterior eye structural change, deposit and degeneration									
Yes	6 (2.2)	6	1.6	7 (2.6)	9	2.6	10 (3.5)	13	3.5
No	2 (1.6)	2	1.2	2 (1.4)	2	1.1	2 (1.7)	2	1.3
Cataract									
Yes	3 (1.1)	3	0.8	4 (1.5)	5	1.4	8 (2.8)	9	2.4
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	0		
Cataract subcapsular									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Cataract cortical									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatochalasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Narrow anterior chamber angle									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Cataract nuclear									
Yes	2 (0.7)	2	0.5	0			1 (0.4)	2	0.5

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Pinguecula									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Posterior capsule opacification									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Ocular infections, irritations and inflammations									
Yes	6 (2.2)	6	1.6	5 (1.9)	6	1.7	4 (1.4)	4	1.1
No	7 (5.6)	7	4.2	3 (2.2)	4	2.2	2 (1.7)	2	1.3
Blepharitis									
Yes	2 (0.7)	2	0.5	0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	2 (1.4)	3	1.6	1 (0.8)	1	0.7
Macular oedema									
Yes	0			2 (0.8)	3	0.9	0		
No	1 (0.8)	1	0.6	0			0		
Meibomian gland dysfunction									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Eyelid rash									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Keratitis									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Ocular hyperaemia									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Conjunctivitis allergic									
Yes	0			0			0		
No	3 (2.4)	3	1.8	0			0		
Episcleritis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Eye pruritus									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Punctate keratitis									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Swelling of eyelid									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Uveitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Eye disorders NEC									
Yes	5 (1.8)	5	1.4	6 (2.3)	6	1.7	6 (2.1)	6	1.6
No	3 (2.4)	3	1.8	2 (1.4)	2	1.1	1 (0.8)	1	0.7
Dry eye									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	0		
Lacrimation increased									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Vitreous disorder									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Eyelid disorder									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Retinal disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Vision disorders									
Yes	5 (1.8)	5	1.4	2 (0.8)	2	0.6	6 (2.1)	6	1.6
No	3 (2.4)	3	1.8	3 (2.2)	3	1.6	2 (1.7)	2	1.3
Vision blurred									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	3 (2.4)	3	1.8	2 (1.4)	2	1.1	1 (0.8)	1	0.7
Myopia									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Visual impairment									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Astigmatism									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Hypermetropia									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Pathologic myopia									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Presbyopia									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Yes	7 (2.5)	9	2.5	5 (1.9)	5	1.4	3 (1.1)	4	1.1
No	3 (2.4)	3	1.8	1 (0.7)	1	0.5	0		
Retinal depigmentation									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Detachment of retinal pigment epithelium									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Macular fibrosis									
Yes	1 (0.4)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			0		
Optic disc disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Retinal degeneration									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Vitreous detachment									
Yes	1 (0.4)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Age-related macular degeneration									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Choroidal dystrophy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Macular degeneration									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Optic atrophy									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Retinal drusen									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Vitreous floaters									
Yes	0			0			1 (0.4)	1	0.3
No	2 (1.6)	2	1.2	0			0		
Glaucoma and ocular hypertension									
Yes	1 (0.4)	1	0.3	1 (0.4)	2	0.6	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Glaucoma									
Yes	1 (0.4)	1	0.3	1 (0.4)	2	0.6	2 (0.7)	2	0.5

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	0		
Ocular haemorrhages and vascular disorders NEC									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Eye haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Conjunctival haemorrhage									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Optic disc haemorrhage									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Ocular neuromuscular disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Eyelid ptosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ocular sensory symptoms NEC									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Asthenopia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Injury, poisoning and procedural complications									
Yes	36 (13.0)	46	12.6	32 (12.1)	43	12.4	34 (12.0)	40	10.7
No	15 (11.9)	25	15.1	16 (11.6)	25	13.5	15 (12.7)	21	13.7
Injuries NEC									
Yes	25 (9.1)	28	7.7	22 (8.3)	26	7.5	23 (8.1)	26	6.9
No	12 (9.5)	21	12.7	10 (7.2)	13	7.0	13 (11.0)	14	9.1
Muscle strain									
Yes	3 (1.1)	3	0.8	5 (1.9)	5	1.4	1 (0.4)	1	0.3
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	0		
Fall									
Yes	7 (2.5)	7	1.9	2 (0.8)	2	0.6	1 (0.4)	2	0.5
No	1 (0.8)	1	0.6	3 (2.2)	4	2.2	1 (0.8)	1	0.7
Skin laceration									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Ligament sprain									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	3 (2.4)	5	3.0	0			4 (3.4)	4	2.6
Limb injury									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	0		
No	2 (1.6)	2	1.2	0			0		
Bone contusion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Contusion									
Yes	0			1 (0.4)	2	0.6	5 (1.8)	5	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	3 (2.5)	4	2.6
Epicondylitis									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Skin abrasion									
Yes	0			0			0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Tooth fracture									
Yes	4 (1.4)	4	1.1	0			3 (1.1)	3	0.8
No	0			1 (0.7)	1	0.5	0		
Animal bite									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Arthropod sting									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Face injury									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Head injury									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Muscle injury									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Post-traumatic pain									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Road traffic accident									
Yes	0			1	(0.4)	1 0.3	1	(0.4)	1 0.3
No	1	(0.8)	1 0.6	0			0		
Traumatic haemothorax									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Abdominal injury									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Arthropod bite									
Yes	0			0			1	(0.4)	1 0.3
No	1	(0.8)	1 0.6	0			0		
Chest injury									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Craniocerebral injury									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Foreign body in eye									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Injury corneal									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Ligament rupture									
Yes	1	(0.4)	1 0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	0			0		
Muscle rupture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Post-traumatic neck syndrome									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Soft tissue injury									
Yes	2 (0.7)	2	0.5	0			0		
No	3 (2.4)	3	1.8	0			0		
Spinal column injury									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Subdural haematoma									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Tendon injury									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Tendon rupture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.8)	1	0.7
Wound									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Bone and joint injuries									
Yes	8 (2.9)	9	2.5	6 (2.3)	10	2.9	9 (3.2)	9	2.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			8 (5.8)	9	4.9	4 (3.4)	4	2.6
Rib fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			3 (2.2)	3	1.6	0		
Foot fracture									
Yes	0			3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Humerus fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			2 (1.4)	2	1.1	0		
Joint injury									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	3 (2.5)	3	2.0
Stress fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Wrist fracture									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Cervical vertebral fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Meniscus injury									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Radius fracture									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Spinal compression fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thoracic vertebral fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Upper limb fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ankle fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Bone fissure									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cartilage injury									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hand fracture									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Hip fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Joint dislocation									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Lisfranc fracture									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Spinal fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Sternal fracture									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Procedural related injuries and complications NEC									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	4 (1.4)	4	1.1
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Post procedural haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Procedural pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Anaemia postoperative									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Graft complication									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dental restoration failure									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Incision site pain									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Post procedural complication									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Surgical skin tear									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Injuries by physical agents									
Yes	1	(0.4)	1 0.3	2	(0.8)	2 0.6	0		
No	1	(0.8)	1 0.6	1	(0.7)	1 0.5	0		
Sunburn									
Yes	0			0			0		
No	0			1	(0.7)	1 0.5	0		
Hypobarism									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Thermal burn									
Yes	0			1	(0.4)	1 0.3	0		
No	1	(0.8)	1 0.6	0			0		
Heat illness									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Medication errors and other product use errors and issues									
Yes	4 (1.4)	6	1.6	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	2	1.2	0			1 (0.8)	2	1.3
Accidental overdose									
Yes	3 (1.1)	5	1.4	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	2	1.3
Extra dose administered									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dose calculation error									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Incorrect dose administered									
Yes	0			0			0		
No	1 (0.8)	2	1.2	0			0		
Overdoses and underdoses NEC									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Intentional overdose									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Respiratory, thoracic and mediastinal disorders									
Yes	26 (9.4)	33	9.1	39 (14.7)	50	14.4	25 (8.8)	27	7.2
No	10 (7.9)	11	6.7	8 (5.8)	12	6.5	11 (9.3)	16	10.4

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Respiratory tract signs and symptoms									
Yes	9 (3.3)	9	2.5	16 (6.0)	16	4.6	8 (2.8)	8	2.1
No	4 (3.2)	4	2.4	3 (2.2)	3	1.6	1 (0.8)	1	0.7
Oropharyngeal pain									
Yes	5 (1.8)	5	1.4	6 (2.3)	6	1.7	5 (1.8)	5	1.3
No	3 (2.4)	3	1.8	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Rhinorrhoea									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Dysphonia									
Yes	0			2 (0.8)	2	0.6	0		
No	0			0			0		
Dry throat									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Aphonia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hiccups									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			0		
Oropharyngeal discomfort									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Painful respiration									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Upper respiratory tract congestion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Nasal discomfort									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Upper-airway cough syndrome									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Respiratory disorders NEC									
Yes	12 (4.3)	13	3.6	14 (5.3)	15	4.3	11 (3.9)	11	2.9
No	4 (3.2)	4	2.4	4 (2.9)	4	2.2	4 (3.4)	7	4.6
Cough									
Yes	6 (2.2)	7	1.9	8 (3.0)	8	2.3	3 (1.1)	3	0.8
No	4 (3.2)	4	2.4	1 (0.7)	1	0.5	4 (3.4)	5	3.3
Productive cough									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			2 (1.4)	2	1.1	0		
Pulmonary mass									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	0		
No	0			1 (0.7)	1	0.5	0		
Respiratory disorder									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	3 (1.1)	3	0.8
No	0			0			0		
Acute respiratory failure									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Sleep apnoea syndrome									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	0			0			0		
Dyspnoea									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Hypoxia									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Upper respiratory tract disorders (excl infections)									
Yes	4 (1.4)	5	1.4	7 (2.6)	8	2.3	5 (1.8)	6	1.6
No	2 (1.6)	2	1.2	3 (2.2)	4	2.2	3 (2.5)	3	2.0
Epistaxis									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	2 (0.7)	2	0.5
No	0			1 (0.7)	2	1.1	3 (2.5)	3	2.0
Rhinitis allergic									
Yes	0			2 (0.8)	2	0.6	0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Sinus congestion									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Nasal congestion									
Yes	1 (0.4)	2	0.5	2 (0.8)	2	0.6	2 (0.7)	3	0.8
No	1 (0.8)	1	0.6	0			0		
Bronchial disorders (excl neoplasms)									
Yes	4 (1.4)	4	1.1	6 (2.3)	8	2.3	1 (0.4)	1	0.3

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	5 (4.2)	5	3.3
Asthma									
Yes	3 (1.1)	3	0.8	5 (1.9)	6	1.7	0		
No	0			0			3 (2.5)	3	2.0
Bronchospasm									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Chronic obstructive pulmonary disease									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Childhood asthma									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Lower respiratory tract disorders (excl obstruction and infection)									
Yes	1 (0.4)	2	0.5	2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Atelectasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Idiopathic interstitial pneumonia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Emphysema									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pleural disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Pneumothorax									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Investigations									
Yes	14 (5.1)	18	4.9	25 (9.4)	31	8.9	22 (7.7)	28	7.5
No	4 (3.2)	5	3.0	15 (10.9)	17	9.2	11 (9.3)	14	9.1
Cardiac and vascular investigations (excl enzyme tests)									
Yes	2 (0.7)	2	0.5	6 (2.3)	7	2.0	3 (1.1)	3	0.8
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Heart rate increased									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Blood pressure decreased									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Blood pressure increased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cardiac murmur									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Cardiac stress test abnormal									

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Carotid pulse decreased												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Electrocardiogram Q waves												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Electrocardiogram QT prolonged												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				1	(0.8)	1	0.7
Electrocardiogram PR prolongation												
Yes	0				0				1	(0.4)	1	0.3
No	0				0				0			
Electrocardiogram ST-T segment abnormal												
Yes	0				0				1	(0.4)	1	0.3
No	0				0				0			
Renal and urinary tract investigations and urinalyses												
Yes	0				2	(0.8)	2	0.6	0			
No	0				4	(2.9)	4	2.2	0			
Glomerular filtration rate decreased												
Yes	0				1	(0.4)	1	0.3	0			
No	0				2	(1.4)	2	1.1	0			
Urine albumin/creatinine ratio increased												

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			2 (1.4)	2	1.1	0		
Urine albumin/creatinine ratio abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal investigations									
Yes	4 (1.4)	4	1.1	5 (1.9)	5	1.4	3 (1.1)	4	1.1
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Lipase increased									
Yes	3 (1.1)	3	0.8	2 (0.8)	2	0.6	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Colonoscopy normal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Occult blood									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Occult blood positive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Amylase increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Faecal volume increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pancreatic enzymes increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Endocrine investigations (incl sex hormones)									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Blood thyroid stimulating hormone increased									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Blood thyroid stimulating hormone decreased									
Yes	0			2 (0.8)	2	0.6	0		
No	0			0			0		
Blood parathyroid hormone increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Haematology investigations (incl blood groups)									
Yes	0			3 (1.1)	4	1.1	1 (0.4)	1	0.3
No	0			1 (0.7)	2	1.1	0		
Haemoglobin decreased									
Yes	0			2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Haematocrit decreased									
Yes	0			1 (0.4)	1	0.3	0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	0		
Platelet count decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Enzyme investigations NEC									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	0		
Blood creatine phosphokinase increased									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	0		
Lipid analyses									
Yes	0			0			1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Lipids abnormal									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Low density lipoprotein increased									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Blood cholesterol increased									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Blood triglycerides increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Hepatobiliary investigations									

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	2 (0.7)	3	0.8	3 (1.1)	3	0.9	4 (1.4)	6	1.6
No	1 (0.8)	1	0.6	0			3 (2.5)	4	2.6
Hepatic enzyme increased									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Liver function test abnormal									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Liver function test increased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Alanine aminotransferase increased									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			2 (1.7)	2	1.3
Aspartate aminotransferase increased									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			0		
Blood bilirubin increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Transaminases increased									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Physical examination and organ system status topics									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Weight decreased									
Yes	0			0			0		
No	0			1	(0.7)	1 0.5	0		
Weight increased									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Reproductive organ and breast investigations (excl hormone analyses)									
Yes	0			0			0		
No	0			1	(0.7)	1 0.5	0		
Mammogram abnormal									
Yes	0			0			0		
No	0			1	(0.7)	1 0.5	0		
Water, electrolyte and mineral investigations									
Yes	2	(0.7)	2 0.5	0			1	(0.4)	1 0.3
No	0			1	(0.7)	1 0.5	0		
Blood potassium increased									
Yes	1	(0.4)	1 0.3	0			0		
No	0			1	(0.7)	1 0.5	0		
Blood potassium decreased									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Blood sodium increased									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Investigations, imaging and histopathology procedures NEC									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Endoscopy abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Metabolic, nutritional and blood gas investigations									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	0			4 (3.4)	5	3.3
Vitamin B12 decreased									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Blood glucose decreased									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Blood glucose increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			3 (2.5)	3	2.0
Blood uric acid increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Brain natriuretic peptide increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Glycosylated haemoglobin increased									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			2 (1.7)	2	1.3
Microbiology and serology investigations									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Helicobacter test positive									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Neurological, special senses and psychiatric investigations									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Intraocular pressure increased									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Protein and chemistry analyses NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
C-reactive protein increased									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Cytogenetic investigations									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Prostatic specific antigen increased									
Yes	0			0			2 (0.7)	2	0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Immunology and allergy investigations									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Antinuclear antibody increased									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Skin and subcutaneous tissue disorders									
Yes	27 (9.8)	29	8.0	29 (10.9)	37	10.6	27 (9.5)	32	8.5
No	11 (8.7)	14	8.5	11 (8.0)	17	9.2	10 (8.5)	10	6.5
Epidermal and dermal conditions									
Yes	16 (5.8)	17	4.7	22 (8.3)	27	7.8	15 (5.3)	16	4.3
No	7 (5.6)	8	4.8	5 (3.6)	8	4.3	7 (5.9)	7	4.6
Rash									
Yes	3 (1.1)	3	0.8	5 (1.9)	6	1.7	2 (0.7)	2	0.5
No	2 (1.6)	2	1.2	2 (1.4)	4	2.2	2 (1.7)	2	1.3
Eczema									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	0			0			0		
Dry skin									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.9	1 (0.4)	1	0.3
No	0			0			0		
Blister									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	2	1.1	0		
Rash pruritic									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			2 (0.8)	2	0.6	0		
No	1 (0.8)	2	1.2	0			1 (0.8)	1	0.7
Drug eruption									
Yes	1 (0.4)	1	0.3	0			3 (1.1)	4	1.1
No	0			1 (0.7)	1	0.5	0		
Skin exfoliation									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Decubitus ulcer									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis allergic									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis contact									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Intertrigo									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Pain of skin									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Perioral dermatitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Pruritus									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Psoriasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Sensitive skin									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Skin burning sensation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Skin lesion									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Dermatitis									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Erythema									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Neurodermatitis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Parapsoriasis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Rash erythematous									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Stasis dermatitis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Xanthelasma									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Skin appendage conditions									
Yes	7 (2.5)	7	1.9	4 (1.5)	4	1.1	7 (2.5)	7	1.9
No	4 (3.2)	4	2.4	5 (3.6)	8	4.3	1 (0.8)	1	0.7
Alopecia									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	2 (1.6)	2	1.2	3 (2.2)	4	2.2	0		
Hyperhidrosis									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	2	1.1	1 (0.8)	1	0.7
Onychomadesis									
Yes	0			0			0		
No	0			1 (0.7)	2	1.1	0		
Acne									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Alopecia areata									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ingrowing nail									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Miliaria									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Nail dystrophy									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Angioedema and urticaria									
Yes	0			0			2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Urticaria									
Yes	0			0			2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Chronic spontaneous urticaria									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Cornification and dystrophic skin disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Actinic keratosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis papillaris capillitii									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperkeratosis									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Punctate keratosis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cutaneous neoplasms benign									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	0			0			0		
Dermal cyst									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.1)	4	1.1
No	0			0			0		
Skin and subcutaneous tissue disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	4	1.1	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Diabetic foot									
Yes	0			1 (0.4)	3	0.9	0		
No	0			0			0		
Skin ulcer									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Skin vascular abnormalities									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			1 (0.8)	1	0.7
Ecchymosis									
Yes	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Haemorrhage subcutaneous									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.8)	1	0.7
Renal and urinary disorders									
Yes	15 (5.4)	17	4.7	26 (9.8)	32	9.2	24 (8.5)	30	8.0
No	4 (3.2)	5	3.0	5 (3.6)	5	2.7	4 (3.4)	4	2.6
Urinary tract signs and symptoms									
Yes	4 (1.4)	4	1.1	13 (4.9)	13	3.7	13 (4.6)	16	4.3
No	3 (2.4)	3	1.8	4 (2.9)	4	2.2	3 (2.5)	3	2.0
Microalbuminuria									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	1 (0.4)	1	0.3
No	0			0			0		
Dysuria									
Yes	0			3 (1.1)	3	0.9	4 (1.4)	4	1.1
No	0			0			0		
Haematuria									
Yes	0			3 (1.1)	3	0.9	1 (0.4)	1	0.3
No	0			0			0		
Nocturia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Proteinuria									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Renal colic									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Pollakiuria									
Yes	0			0			2 (0.7)	2	0.5
No	3 (2.4)	3	1.8	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Lower urinary tract symptoms									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Micturition disorder									
Yes	0			0			1 (0.4)	2	0.5
No	0			0			0		
Polyuria									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Urethral pain									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Urinary incontinence									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Nephropathies									
Yes	3 (1.1)	3	0.8	5 (1.9)	5	1.4	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Diabetic nephropathy									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Nephropathy									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Renal disorders (excl nephropathies)									
Yes	4 (1.4)	4	1.1	6 (2.3)	8	2.3	7 (2.5)	7	1.9
No	1 (0.8)	1	0.6	0			0		
Acute kidney injury									
Yes	2 (0.7)	2	0.5	3 (1.1)	4	1.1	2 (0.7)	2	0.5
No	0			0			0		
Renal cyst									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	3 (1.1)	3	0.8
No	0			0			0		
Chronic kidney disease									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Renal impairment									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hydronephrosis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Kidney fibrosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Urolithiases									
Yes	5 (1.8)	6	1.6	4 (1.5)	4	1.1	5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Nephrolithiasis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	5 (1.8)	6	1.6	2 (0.8)	2	0.6	3 (1.1)	3	0.8
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Calculus urinary									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Stag horn calculus									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ureterolithiasis									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Bladder and bladder neck disorders (excl calculi)									
Yes	0			2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Bladder outlet obstruction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hypertonic bladder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Bladder hypertrophy									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Vascular disorders									
Yes	19 (6.9)	20	5.5	14 (5.3)	16	4.6	24 (8.5)	25	6.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	3 (2.4)	3	1.8	10 (7.2)	10	5.4	6 (5.1)	7	4.6
Vascular hypertensive disorders									
Yes	7 (2.5)	7	1.9	5 (1.9)	6	1.7	12 (4.2)	12	3.2
No	2 (1.6)	2	1.2	5 (3.6)	5	2.7	3 (2.5)	4	2.6
Hypertension									
Yes	7 (2.5)	7	1.9	5 (1.9)	6	1.7	9 (3.2)	9	2.4
No	2 (1.6)	2	1.2	5 (3.6)	5	2.7	3 (2.5)	3	2.0
Hypertensive crisis									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.8)	1	0.7
Hypertensive urgency									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Decreased and nonspecific blood pressure disorders and shock									
Yes	5 (1.8)	6	1.6	2 (0.8)	3	0.9	3 (1.1)	3	0.8
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Hypotension									
Yes	4 (1.4)	5	1.4	0			1 (0.4)	1	0.3
No	0			2 (1.4)	2	1.1	0		
Blood pressure inadequately controlled									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Orthostatic hypotension									
Yes	0			1 (0.4)	2	0.6	1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Shock									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Vascular disorders NEC									
Yes	1 (0.4)	1	0.3	2 (0.8)	2	0.6	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Aortic dilatation									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Aortic rupture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hot flush									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Vascular haemorrhagic disorders									
Yes	0			3 (1.1)	3	0.9	0		
No	0			0			1 (0.8)	1	0.7
Haematoma									
Yes	0			3 (1.1)	3	0.9	0		
No	0			0			1 (0.8)	1	0.7
Embolism and thrombosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Post thrombotic syndrome									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Deep vein thrombosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Vascular infections and inflammations									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Temporal arteritis									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Aneurysms and artery dissections									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Aortic aneurysm									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Yes	6 (2.2)	6	1.6	1 (0.4)	1	0.3	5 (1.8)	6	1.6
No	0			0			0		
Aortic arteriosclerosis									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	0		
No	0			0			0		
Arteriosclerosis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Peripheral arterial occlusive disease									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Peripheral artery stenosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Peripheral coldness									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Peripheral venous disease									
Yes	0			0			2 (0.7)	3	0.8
No	0			0			0		
Lymphatic vessel disorders									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Lymphoedema									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Venous varices									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Varicose vein									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Psychiatric disorders									
Yes	14 (5.1)	19	5.2	17 (6.4)	22	6.3	12 (4.2)	13	3.5
No	9 (7.1)	9	5.4	7 (5.1)	7	3.8	3 (2.5)	3	2.0

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Sleep disorders and disturbances									
Yes	3 (1.1)	3	0.8	8 (3.0)	8	2.3	2 (0.7)	2	0.5
No	3 (2.4)	3	1.8	2 (1.4)	2	1.1	2 (1.7)	2	1.3
Insomnia									
Yes	3 (1.1)	3	0.8	6 (2.3)	6	1.7	2 (0.7)	2	0.5
No	3 (2.4)	3	1.8	1 (0.7)	1	0.5	2 (1.7)	2	1.3
Sleep disorder									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Abnormal dreams									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Middle insomnia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Depressed mood disorders and disturbances									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.9	5 (1.8)	5	1.3
No	3 (2.4)	3	1.8	4 (2.9)	4	2.2	0		
Depressed mood									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	0		
Depression									
Yes	0			2 (0.8)	2	0.6	5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	0			0		
Anhedonia									
Yes	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.7)	1	0.5	0		
Major depression									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Anxiety disorders and symptoms									
Yes	9 (3.3)	10	2.7	4 (1.5)	4	1.1	5 (1.8)	5	1.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Anxiety									
Yes	6 (2.2)	7	1.9	3 (1.1)	3	0.9	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	0			0		
Anxiety disorder due to a general medical condition									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Stress									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Generalised anxiety disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Nervousness									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Post-traumatic stress disorder									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Adjustment disorders (incl subtypes)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	0		
No	0			0			0		
Adjustment disorder with depressed mood									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Grief reaction									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Mood disorders and disturbances NEC									
Yes	1 (0.4)	1	0.3	2 (0.8)	3	0.9	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Irritability									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Mood altered									
Yes	0			1 (0.4)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Mood swings									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Changes in physical activity									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Restlessness									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Suicidal and self-injurious behaviours NEC									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Suicidal ideation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Psychiatric disorders NEC									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Mental status changes									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Sexual dysfunctions, disturbances and gender identity disorders									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Libido decreased									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Cardiac disorders									
Yes	14 (5.1)	18	4.9	16 (6.0)	22	6.3	8 (2.8)	8	2.1
No	6 (4.8)	6	3.6	6 (4.3)	6	3.2	5 (4.2)	9	5.9
Cardiac arrhythmias									
Yes	6 (2.2)	8	2.2	11 (4.2)	14	4.0	2 (0.7)	2	0.5
No	4 (3.2)	4	2.4	2 (1.4)	2	1.1	2 (1.7)	3	2.0

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Atrial fibrillation									
Yes	2 (0.7)	2	0.5	5 (1.9)	5	1.4	2 (0.7)	2	0.5
No	0			0			0		
Supraventricular extrasystoles									
Yes	0			4 (1.5)	4	1.1	0		
No	0			0			0		
Tachycardia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Atrioventricular block first degree									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Bundle branch block right									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Sinus tachycardia									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Supraventricular tachycardia									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Ventricular extrasystoles									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Atrial flutter									
Yes	0			0			0		
No	0			0			1 (0.8)	2	1.3

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bradycardia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Bundle branch block left									
Yes	1 (0.4)	1	0.3	0			0		
No	2 (1.6)	2	1.2	0			0		
Coronary artery disorders									
Yes	6 (2.2)	6	1.6	3 (1.1)	3	0.9	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	4 (2.9)	4	2.2	0		
Angina pectoris									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Coronary artery disease									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Myocardial infarction									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.7)	1	0.5	0		
Myocardial ischaemia									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Acute myocardial infarction									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Angina unstable									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Arteriosclerosis coronary artery									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cardiac disorders, signs and symptoms NEC									
Yes	2 (0.7)	2	0.5	3 (1.1)	4	1.1	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			3 (2.5)	3	2.0
Palpitations									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	0		
No	1 (0.8)	1	0.6	0			2 (1.7)	2	1.3
Cardiovascular disorder									
Yes	0			1 (0.4)	2	0.6	1 (0.4)	1	0.3
No	0			0			0		
Hypertensive heart disease									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Heart failures									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			1 (0.8)	2	1.3
Cardiac failure congestive									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Cardiac failure acute									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Left ventricular failure									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (0.8)	1	0.7
Myocardial disorders									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.8)	1	0.7
Cardiac hypertrophy									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Left ventricular hypertrophy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Ear and labyrinth disorders									
Yes	9 (3.3)	12	3.3	15 (5.7)	15	4.3	8 (2.8)	10	2.7
No	2 (1.6)	2	1.2	5 (3.6)	5	2.7	4 (3.4)	4	2.6
Inner ear and VIIIth cranial nerve disorders									
Yes	7 (2.5)	10	2.7	8 (3.0)	8	2.3	5 (1.8)	6	1.6
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	3 (2.5)	3	2.0
Vertigo									
Yes	3 (1.1)	5	1.4	7 (2.6)	7	2.0	5 (1.8)	6	1.6
No	0			0			1 (0.8)	1	0.7
Vertigo positional									
Yes	0			1 (0.4)	1	0.3	0		
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Motion sickness									
Yes	1 (0.4)	2	0.5	0			0		
No	1 (0.8)	1	0.6	0			0		

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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tinnitus									
Yes	3 (1.1)	3	0.8	0			0		
No	0			0			1 (0.8)	1	0.7
Aural disorders NEC									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	0			2 (1.4)	2	1.1	1 (0.8)	1	0.7
Ear pain									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	0			1 (0.7)	1	0.5	0		
Ear pruritus									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Ear discomfort									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Hearing disorders									
Yes	0			2 (0.8)	2	0.6	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Hypoacusis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Deafness bilateral									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Deafness unilateral									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mixed deafness									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
External ear disorders (excl congenital)									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Cerumen impaction									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Excessive cerumen production									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Reproductive system and breast disorders									
Yes	8 (2.9)	9	2.5	7 (2.6)	7	2.0	5 (1.8)	7	1.9
No	7 (5.6)	11	6.7	5 (3.6)	5	2.7	4 (3.4)	4	2.6
Menstrual cycle and uterine bleeding disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	2	0.5
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	0		
Metrorrhagia									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Oligomenorrhoea									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		

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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dysmenorrhoea									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Menorrhagia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Menstruation irregular									
Yes	0			0			1 (0.4)	2	0.5
No	1 (0.8)	1	0.6	0			0		
Vulvovaginal disorders (excl infections and inflammations)									
Yes	0			2 (0.8)	2	0.6	2 (0.7)	2	0.5
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Vulval disorder									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Vulva cyst									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vulvovaginal pruritus									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vaginal disorder									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Vaginal haemorrhage									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	0			0		
Vulvovaginal dryness									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Sexual function and fertility disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Erectile dysfunction									
Yes	0			1 (0.4)	1	0.3	0		
No	2 (1.6)	2	1.2	1 (0.7)	1	0.5	1 (0.8)	1	0.7
Menopause related conditions									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Atrophic vulvovaginitis									
Yes	0			0			1 (0.4)	1	0.3
No	0			1 (0.7)	1	0.5	0		
Breast disorders									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Breast mass									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Breast cyst									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Breast pain									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Reproductive tract disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Pruritus genital									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Pelvic pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Uterine, pelvic and broad ligament disorders									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Uterine polyp									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Adenomyosis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Endometriosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Male reproductive tract infections and inflammations									
Yes	2 (0.7)	2	0.5	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	2 (1.6)	2	1.2	0			1 (0.8)	1	0.7
Balanoposthitis									
Yes	2 (0.7)	2	0.5	0			0		
No	1 (0.8)	1	0.6	0			0		
Prostatitis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			1 (0.8)	1	0.7
Ovarian and fallopian tube disorders									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			0		
Haemorrhagic ovarian cyst									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Ovarian cyst									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Penile and scrotal disorders (excl infections and inflammations)									
Yes	0			0			0		
No	1 (0.8)	2	1.2	0			0		
Penile erosion									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Peyronie's disease									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Prostatic disorders (excl infections and inflammations)									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			1 (0.8)	1	0.7
Benign prostatic hyperplasia									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			1 (0.8)	1	0.7
Testicular and epididymal disorders									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Testicular disorder									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Blood and lymphatic system disorders									
Yes	4 (1.4)	4	1.1	8 (3.0)	9	2.6	8 (2.8)	9	2.4
No	5 (4.0)	5	3.0	4 (2.9)	4	2.2	2 (1.7)	2	1.3
Anaemias nonhaemolytic and marrow depression									
Yes	3 (1.1)	3	0.8	7 (2.6)	8	2.3	5 (1.8)	5	1.3
No	5 (4.0)	5	3.0	3 (2.2)	3	1.6	1 (0.8)	1	0.7
Anaemia									
Yes	2 (0.7)	2	0.5	6 (2.3)	6	1.7	3 (1.1)	3	0.8
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	1 (0.8)	1	0.7
Iron deficiency anaemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Pancytopenia												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Hypochromic anaemia												
Yes	0				0				0			
No	1	(0.8)	1	0.6	0				0			
Microcytic anaemia												
Yes	0				0				0			
No	1	(0.8)	1	0.6	0				0			
Normocytic anaemia												
Yes	0				0				1	(0.4)	1	0.3
No	0				0				0			
Spleen, lymphatic and reticuloendothelial system disorders												
Yes	0				0				3	(1.1)	3	0.8
No	0				1	(0.7)	1	0.5	0			
Splenomegaly												
Yes	0				0				1	(0.4)	1	0.3
No	0				1	(0.7)	1	0.5	0			
Lymphadenopathy												
Yes	0				0				2	(0.7)	2	0.5
No	0				0				0			
Platelet disorders												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Thrombocytosis												
Yes	0				1	(0.4)	1	0.3	0			

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
White blood cell disorders									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Leukocytosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			1 (0.8)	1	0.7
Lymphopenia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hepatobiliary disorders									
Yes	6 (2.2)	6	1.6	6 (2.3)	9	2.6	7 (2.5)	12	3.2
No	4 (3.2)	5	3.0	4 (2.9)	4	2.2	2 (1.7)	2	1.3
Hepatic and hepatobiliary disorders									
Yes	4 (1.4)	4	1.1	5 (1.9)	6	1.7	7 (2.5)	8	2.1
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	2 (1.7)	2	1.3
Hepatic steatosis									
Yes	3 (1.1)	3	0.8	2 (0.8)	2	0.6	5 (1.8)	5	1.3
No	0			2 (1.4)	2	1.1	0		
Hepatic cyst									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	1 (0.8)	1	0.7
Hepatic lesion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Non-alcoholic steatohepatitis									

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Nonalcoholic fatty liver disease									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Portal vein thrombosis									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Drug-induced liver injury									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Hepatic cirrhosis									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Hepatomegaly									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Liver disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Portal hypertension									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Gallbladder disorders									
Yes	2 (0.7)	2	0.5	2 (0.8)	3	0.9	3 (1.1)	4	1.1
No	2 (1.6)	3	1.8	1 (0.7)	1	0.5	0		
Gallbladder polyp									

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Cholecystitis chronic									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cholelithiasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.1)	3	0.8
No	2 (1.6)	2	1.2	0			0		
Cholecystitis acute									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Yes	11 (4.0)	14	3.8	6 (2.3)	7	2.0	11 (3.9)	13	3.5
No	2 (1.6)	2	1.2	3 (2.2)	3	1.6	1 (0.8)	1	0.7
Leukaemias									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Chronic lymphocytic leukaemia									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Myeloid leukaemia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal neoplasms benign									
Yes	3 (1.1)	4	1.1	2 (0.8)	2	0.6	2 (0.7)	2	0.5

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Benign duodenal neoplasm									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal tract adenoma									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Colon adenoma									
Yes	3 (1.1)	4	1.1	0			2 (0.7)	2	0.5
No	0			0			0		
Cutaneous neoplasms benign									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Anogenital warts									
Yes	0			0			0		
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Melanocytic naevus									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Lymphomas non-Hodgkin's unspecified histology									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Gastrointestinal lymphoma									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Miscellaneous and site unspecified neoplasms malignant and unspecified									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Squamous cell carcinoma									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.8)	1	0.7
Nasal cavity cancer									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Keratinising squamous cell carcinoma of nasopharynx									
Yes	0			0			0		
No	0			0			1 (0.8)	1	0.7
Skeletal neoplasms benign									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Osteochondroma									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Soft tissue neoplasms benign									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lipoma									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Breast neoplasms malignant and unspecified (incl nipple)									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Invasive ductal breast carcinoma									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Endocrine neoplasms benign									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Pituitary tumour benign									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Endocrine neoplasms malignant and unspecified									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Neuroendocrine tumour									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal neoplasms malignant and unspecified									
Yes	5 (1.8)	5	1.4	0			2 (0.7)	2	0.5
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Adenocarcinoma gastric									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Adenocarcinoma of colon									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Gastric cancer									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Gastric cancer stage IV									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Gastrointestinal stromal tumour									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Gastrointestinal submucosal tumour									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Oral neoplasm									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Hepatobiliary neoplasms malignant and unspecified									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Hepatocellular carcinoma									
Yes	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Metastases									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Metastases to liver									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms female benign									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Uterine leiomyoma									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms female malignant and unspecified									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Uterine cancer									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms male malignant and unspecified									
Yes	0			0			3	(1.1)	3 0.8
No	0			0			0		
Prostate cancer									
Yes	0			0			3	(1.1)	3 0.8
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Skin neoplasms malignant and unspecified									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Basal cell carcinoma									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Immune system disorders									
Yes	4 (1.4)	4	1.1	6 (2.3)	6	1.7	6 (2.1)	7	1.9
No	2 (1.6)	2	1.2	0			0		
Allergic conditions									
Yes	4 (1.4)	4	1.1	6 (2.3)	6	1.7	6 (2.1)	7	1.9
No	1 (0.8)	1	0.6	0			0		
Seasonal allergy									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	4 (1.4)	5	1.3
No	0			0			0		
Allergy to arthropod sting									
Yes	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
No	0			0			0		
Hypersensitivity									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.6	0			0		
Allergy to chemicals									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Drug hypersensitivity									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Multiple allergies									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Immune disorders NEC									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Immunisation reaction									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Endocrine disorders									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	0		
Thyroid gland disorders									
Yes	2 (0.7)	2	0.5	2 (0.8)	2	0.6	4 (1.4)	4	1.1
No	1 (0.8)	1	0.6	2 (1.4)	2	1.1	0		
Hypothyroidism									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			1 (0.7)	1	0.5	0		
Thyroid cyst									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Primary hyperthyroidism									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Autoimmune thyroiditis									
Yes	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
No	0			0			0		
Goitre									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Silent thyroiditis									
Yes	0			0			0		
No	1 (0.8)	1	0.6	0			0		
Thyroid mass									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Surgical and medical procedures									
Yes	2 (0.7)	2	0.5	0			5 (1.8)	6	1.6
No	1 (0.8)	1	0.6	1 (0.7)	1	0.5	0		
Endocrine gland therapeutic procedures									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Thyroidectomy									
Yes	0			0			0		
No	0			1 (0.7)	1	0.5	0		
Bone and joint therapeutic procedures									
Yes	0			0			1 (0.4)	1	0.3
No	1 (0.8)	1	0.6	0			0		
Bone graft									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.6	0			0		
Joint injection									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Cardiac therapeutic procedures									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cardiac pacemaker replacement									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Eye therapeutic procedures									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Cataract operation									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Head and neck therapeutic procedures									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tooth extraction									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Male genital tract therapeutic procedures									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Sperm aspiration									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Therapeutic procedures and supportive care NEC									
Yes	0			0			3	(1.1)	3 0.8
No	0			0			0		
Cyst removal									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Nerve block									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Stent placement									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			0		
Congenital, familial and genetic disorders									
Yes	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
No	0			0			1	(0.8)	1 0.7
Reproductive tract and breast disorders congenital									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			1	(0.8)	1 0.7
Phimosis									
Yes	0			0			1	(0.4)	1 0.3
No	0			0			1	(0.8)	1 0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Respiratory disorders congenital									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Laryngeal web									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Pregnancy, puerperium and perinatal conditions									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Abortions and stillbirth									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Abortion spontaneous									
Yes	0			0			1 (0.4)	1	0.3
No	0			0			0		
Social circumstances									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			0		
Economic and housing issues									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			0		
Stress at work									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.6	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

35 Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Yes	87	118.1			178	245.5			80	112.7		
No	13	18.1			21	29.5			21	29.1		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Yes	70	(80.5)	433	366.6	152	(85.4)	747	304.3	62	(77.5)	178	157.9
No	12	(92.3)	50	276.1	19	(90.5)	87	294.9	18	(85.7)	57	195.7
Serious												
Yes												
Yes	7	(8.0)	10	8.5	8	(4.5)	9	3.7	5	(6.3)	5	4.4
No	0				2	(9.5)	3	10.2	2	(9.5)	2	6.9
No												
Yes	70	(80.5)	423	358.2	151	(84.8)	738	300.6	61	(76.3)	173	153.5
No	12	(92.3)	50	276.1	19	(90.5)	84	284.7	17	(81.0)	55	188.8
Severity												
Severe												
Yes	3	(3.4)	3	2.5	3	(1.7)	4	1.6	4	(5.0)	4	3.5
No	0				0				1	(4.8)	1	3.4
Moderate												
Yes	13	(14.9)	61	51.7	20	(11.2)	34	13.8	7	(8.8)	9	8.0
No	1	(7.7)	2	11.0	5	(23.8)	8	27.1	4	(19.0)	4	13.7
Mild												
Yes	67	(77.0)	369	312.5	150	(84.3)	709	288.8	60	(75.0)	165	146.4
No	12	(92.3)	48	265.0	18	(85.7)	79	267.8	16	(76.2)	52	178.5

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Missing									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Probable									
Yes	22 (25.3)	58	49.1	48 (27.0)	148	60.3	8 (10.0)	10	8.9
No	3 (23.1)	3	16.6	7 (33.3)	10	33.9	2 (9.5)	6	20.6
Possible									
Yes	46 (52.9)	181	153.3	74 (41.6)	179	72.9	8 (10.0)	15	13.3
No	9 (69.2)	9	49.7	10 (47.6)	27	91.5	2 (9.5)	2	6.9
Unlikely									
Yes	64 (73.6)	194	164.3	135 (75.8)	419	170.7	56 (70.0)	153	135.8
No	9 (69.2)	38	209.8	17 (81.0)	50	169.5	18 (85.7)	49	168.2
Outcome									
Recovered									
Yes	66 (75.9)	377	319.2	147 (82.6)	652	265.6	58 (72.5)	142	126.0
No	12 (92.3)	32	176.7	17 (81.0)	77	261.0	17 (81.0)	44	151.0
Recovering									
Yes	6 (6.9)	10	8.5	12 (6.7)	16	6.5	4 (5.0)	4	3.5
No	3 (23.1)	6	33.1	4 (19.0)	5	16.9	1 (4.8)	1	3.4
Not Recovered									
Yes	28 (32.2)	46	39.0	51 (28.7)	79	32.2	18 (22.5)	32	28.4
No	7 (53.8)	12	66.3	3 (14.3)	5	16.9	8 (38.1)	12	41.2
Leading to									
Permanent treatment discontinuation									
Yes	3 (3.4)	6	5.1	5 (2.8)	9	3.7	0		
No	0			0			1 (4.8)	1	3.4

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by dyslipidaemia at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Leading to												
Temporary interruption of trial product												
Yes	6	(6.9)	8	6.8	12	(6.7)	23	9.4	4	(5.0)	4	3.5
No	1	(7.7)	1	5.5	2	(9.5)	3	10.2	1	(4.8)	1	3.4
Dose reduction of trial product												
Yes	3	(3.4)	3	2.5	11	(6.2)	16	6.5	0			
No	0				3	(14.3)	3	10.2	0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

36 Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Yes	87		118.1		178		245.5		80		112.7	
No	13		18.1		21		29.5		21		29.1	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Yes	70	(80.5)	433	366.6	152	(85.4)	747	304.3	62	(77.5)	178	157.9
No	12	(92.3)	50	276.1	19	(90.5)	87	294.9	18	(85.7)	57	195.7
Gastrointestinal disorders												
Yes	53	(60.9)	236	199.8	104	(58.4)	303	123.4	23	(28.8)	30	26.6
No	11	(84.6)	20	110.4	14	(66.7)	40	135.6	7	(33.3)	13	44.6
Gastrointestinal signs and symptoms												
Yes	34	(39.1)	145	122.8	62	(34.8)	151	61.5	8	(10.0)	10	8.9
No	5	(38.5)	6	33.1	9	(42.9)	18	61.0	3	(14.3)	7	24.0
Nausea												
Yes	16	(18.4)	24	20.3	29	(16.3)	59	24.0	4	(5.0)	4	3.5
No	2	(15.4)	3	16.6	6	(28.6)	7	23.7	0			
Vomiting												
Yes	10	(11.5)	34	28.8	14	(7.9)	24	9.8	1	(1.3)	1	0.9
No	0				3	(14.3)	5	16.9	1	(4.8)	1	3.4
Abdominal pain												
Yes	3	(3.4)	4	3.4	10	(5.6)	13	5.3	0			
No	0				2	(9.5)	3	10.2	0			
Abdominal discomfort												
Yes	10	(11.5)	11	9.3	11	(6.2)	15	6.1	1	(1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	0		
Abdominal pain upper									
Yes	3 (3.4)	5	4.2	9 (5.1)	12	4.9	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Faeces soft									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			1 (4.8)	1	3.4	0		
Dyspepsia									
Yes	5 (5.7)	16	13.5	9 (5.1)	14	5.7	0		
No	1 (7.7)	1	5.5	0			1 (4.8)	4	13.7
Abdominal distension									
Yes	6 (6.9)	7	5.9	7 (3.9)	8	3.3	2 (2.5)	3	2.7
No	1 (7.7)	1	5.5	0			0		
Eructation									
Yes	4 (4.6)	21	17.8	2 (1.1)	2	0.8	0		
No	0			0			0		
Abdominal tenderness									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Faeces hard									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Flatulence									
Yes	1 (1.1)	18	15.2	1 (0.6)	1	0.4	0		
No	0			0			0		
Abdominal pain lower									
Yes	1 (1.1)	2	1.7	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (4.8)	2	6.9
Epigastric discomfort									
Yes	2 (2.3)	2	1.7	0			0		
No	0			0			0		
Gastrointestinal motility and defaecation conditions									
Yes	34 (39.1)	74	62.7	70 (39.3)	103	42.0	7 (8.8)	7	6.2
No	7 (53.8)	10	55.2	8 (38.1)	16	54.2	2 (9.5)	2	6.9
Constipation									
Yes	15 (17.2)	18	15.2	44 (24.7)	52	21.2	3 (3.8)	3	2.7
No	4 (30.8)	4	22.1	8 (38.1)	8	27.1	0		
Diarrhoea									
Yes	18 (20.7)	53	44.9	28 (15.7)	44	17.9	4 (5.0)	4	3.5
No	4 (30.8)	6	33.1	4 (19.0)	8	27.1	2 (9.5)	2	6.9
Gastrooesophageal reflux disease									
Yes	2 (2.3)	2	1.7	6 (3.4)	6	2.4	0		
No	0			0			0		
Gastrointestinal motility disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Irritable bowel syndrome									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Dental and gingival conditions									
Yes	6 (6.9)	6	5.1	12 (6.7)	13	5.3	4 (5.0)	4	3.5
No	0			2 (9.5)	2	6.8	2 (9.5)	2	6.9
Dental caries									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	4 (4.6)	4	3.4	9 (5.1)	10	4.1	3 (3.8)	3	2.7
No	0			2 (9.5)	2	6.8	2 (9.5)	2	6.9
Toothache									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Tooth impacted									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Dental cyst									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Gastrointestinal inflammatory conditions									
Yes	1 (1.1)	1	0.8	9 (5.1)	9	3.7	4 (5.0)	4	3.5
No	0			1 (4.8)	2	6.8	1 (4.8)	1	3.4
Gastritis									
Yes	0			2 (1.1)	2	0.8	3 (3.8)	3	2.7
No	0			1 (4.8)	1	3.4	0		
Enteritis									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Enterocolitis									
Yes	1 (1.1)	1	0.8	4 (2.2)	4	1.6	1 (1.3)	1	0.9
No	0			0			0		
Chronic gastritis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Colitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Colitis ischaemic									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Benign neoplasms gastrointestinal									
Yes	3 (3.4)	3	2.5	5 (2.8)	6	2.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Large intestine polyp									
Yes	2 (2.3)	2	1.7	3 (1.7)	3	1.2	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Gastric polyps									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Rectal polyp									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Oral soft tissue conditions									
Yes	0			2 (1.1)	2	0.8	0		
No	0			1 (4.8)	1	3.4	0		
Stomatitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			1 (4.8)	1	3.4	0		
Angular cheilitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal conditions NEC									
Yes	4 (4.6)	4	3.4	10 (5.6)	12	4.9	1 (1.3)	1	0.9
No	0			0			0		
Gastrointestinal disorder									
Yes	2 (2.3)	2	1.7	4 (2.2)	6	2.4	0		
No	0			0			0		
Food poisoning									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Gastric disorder									
Yes	2 (2.3)	2	1.7	3 (1.7)	3	1.2	0		
No	0			0			0		
Barrett's oesophagus									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Gastrointestinal haemorrhages NEC									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Anal haemorrhage									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Mallory-Weiss syndrome									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Anal and rectal conditions NEC									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Anal fissure									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		
Diverticular disorders									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		
Diverticulum intestinal									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		
Gastrointestinal ulceration and perforation									
Yes	0			1 (0.6)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Erosive duodenitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Gastritis erosive									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Gastrointestinal vascular conditions									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	2 (15.4)	2	11.0	0			0		
Haemorrhoids									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	2 (15.4)	2	11.0	0			0		
Gastrointestinal stenosis and obstruction									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Intestinal obstruction									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Salivary gland conditions									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Parotid gland enlargement									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Infections and infestations									
Yes	37 (42.5)	55	46.6	70 (39.3)	136	55.4	29 (36.3)	43	38.2
No	5 (38.5)	9	49.7	10 (47.6)	17	57.6	6 (28.6)	10	34.3
Infections - pathogen unspecified									
Yes	34 (39.1)	50	42.3	63 (35.4)	117	47.7	28 (35.0)	42	37.3
No	5 (38.5)	8	44.2	8 (38.1)	15	50.8	6 (28.6)	9	30.9
Nasopharyngitis									
Yes	21 (24.1)	30	25.4	46 (25.8)	70	28.5	14 (17.5)	19	16.9
No	3 (23.1)	6	33.1	7 (33.3)	11	37.3	4 (19.0)	5	17.2
Gastroenteritis									
Yes	7 (8.0)	8	6.8	10 (5.6)	12	4.9	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Pharyngitis									
Yes	3 (3.4)	3	2.5	2 (1.1)	3	1.2	4 (5.0)	5	4.4
No	0			1 (4.8)	1	3.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Conjunctivitis									
Yes	0			1 (0.6)	2	0.8	2 (2.5)	2	1.8
No	0			1 (4.8)	1	3.4	0		
Pyelonephritis acute									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Bronchitis									
Yes	2 (2.3)	2	1.7	6 (3.4)	9	3.7	0		
No	1 (7.7)	1	5.5	0			0		
Cystitis									
Yes	1 (1.1)	1	0.8	3 (1.7)	3	1.2	0		
No	0			0			1 (4.8)	2	6.9
Rhinitis									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	2 (2.5)	2	1.8
No	0			0			0		
Tonsillitis									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	3 (3.8)	4	3.5
No	0			0			0		
Acute sinusitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Diverticulitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Enteritis infectious									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Folliculitis									
Yes	0			1 (0.6)	2	0.8	0		
No	0			0			0		
Gingivitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Hordeolum									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Pelvic inflammatory disease									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Pyelonephritis									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Sinusitis									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	3 (3.8)	3	2.7
No	0			0			0		
Urethritis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Urinary tract infection									
Yes	0			1 (0.6)	3	1.2	0		
No	1 (7.7)	1	5.5	0			0		
Periodontitis									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pyoderma									
Yes	0			0			0		
No	0			0			1 (4.8)	2	6.9
Upper respiratory tract infection									
Yes	0			0			2 (2.5)	3	2.7
No	0			0			0		
Vaginal infection									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Viral infectious disorders									
Yes	4 (4.6)	4	3.4	12 (6.7)	13	5.3	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	0		
Influenza									
Yes	2 (2.3)	2	1.7	7 (3.9)	7	2.9	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Herpes zoster									
Yes	1 (1.1)	1	0.8	3 (1.7)	3	1.2	0		
No	0			0			0		
Gastroenteritis viral									
Yes	0			2 (1.1)	2	0.8	0		
No	1 (7.7)	1	5.5	0			0		
Herpes simplex									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Infectious mononucleosis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Fungal infectious disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			1 (4.8)	1	3.4	0		
Tinea pedis									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Vulvovaginal candidiasis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Bacterial infectious disorders									
Yes	1 (1.1)	1	0.8	4 (2.2)	5	2.0	0		
No	0			0			1 (4.8)	1	3.4
Alpha haemolytic streptococcal infection									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Cellulitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Erysipelas									
Yes	0			1 (0.6)	2	0.8	0		
No	0			0			0		
Furuncle									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Helicobacter infection									
Yes	1 (1.1)	1	0.8	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (4.8)	1	3.4
Musculoskeletal and connective tissue disorders									
Yes	21 (24.1)	31	26.2	37 (20.8)	46	18.7	17 (21.3)	24	21.3
No	3 (23.1)	3	16.6	6 (28.6)	6	20.3	7 (33.3)	10	34.3
Musculoskeletal and connective tissue disorders NEC									
Yes	10 (11.5)	14	11.9	20 (11.2)	21	8.6	11 (13.8)	13	11.5
No	0			2 (9.5)	2	6.8	2 (9.5)	2	6.9
Back pain									
Yes	8 (9.2)	12	10.2	17 (9.6)	18	7.3	9 (11.3)	11	9.8
No	0			2 (9.5)	2	6.8	0		
Musculoskeletal discomfort									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Neck pain									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Pain in extremity									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			1 (4.8)	1	3.4
Musculoskeletal pain									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Musculoskeletal stiffness									
Yes	1 (1.1)	1	0.8	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Joint disorders									
Yes	13 (14.9)	15	12.7	11 (6.2)	11	4.5	7 (8.8)	9	8.0
No	2 (15.4)	2	11.0	2 (9.5)	2	6.8	4 (19.0)	7	24.0
Osteoarthritis									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	0		
Rotator cuff syndrome									
Yes	0			0			0		
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	1 (4.8)	1	3.4
Arthralgia									
Yes	9 (10.3)	10	8.5	5 (2.8)	5	2.0	5 (6.3)	7	6.2
No	0			0			1 (4.8)	2	6.9
Periarthritis									
Yes	2 (2.3)	2	1.7	4 (2.2)	4	1.6	0		
No	0			0			1 (4.8)	1	3.4
Spinal osteoarthritis									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Arthritis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Articular calcification									
Yes	0			0			0		
No	0			0			1 (4.8)	2	6.9
Muscle disorders									
Yes	0			8 (4.5)	8	3.3	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	0		
Rhabdomyolysis									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Myalgia									
Yes	0			4 (2.2)	4	1.6	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Muscle spasms									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Fibromyalgia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Intervertebral disc protrusion									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Spinal stenosis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Tendon, ligament and cartilage disorders									
Yes	1 (1.1)	1	0.8	3 (1.7)	4	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Tendonitis									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	0		
No	0			0			0		
Trigger finger									
Yes	0			1 (0.6)	2	0.8	0		
No	0			0			0		
Synovial and bursal disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Bursitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Synovitis									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Metabolism and nutrition disorders									
Yes	5 (5.7)	5	4.2	19 (10.7)	20	8.1	6 (7.5)	9	8.0
No	1 (7.7)	1	5.5	4 (19.0)	4	13.6	2 (9.5)	2	6.9
Appetite and general nutritional disorders									
Yes	4 (4.6)	4	3.4	10 (5.6)	10	4.1	0		
No	1 (7.7)	1	5.5	3 (14.3)	3	10.2	0		
Decreased appetite									
Yes	4 (4.6)	4	3.4	10 (5.6)	10	4.1	0		
No	1 (7.7)	1	5.5	3 (14.3)	3	10.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lipid metabolism disorders									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Dyslipidaemia									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Purine and pyrimidine metabolism disorders									
Yes	1 (1.1)	1	0.8	4 (2.2)	4	1.6	4 (5.0)	5	4.4
No	0			0			0		
Gout									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	2	1.8
No	0			0			0		
Hyperuricaemia									
Yes	0			2 (1.1)	2	0.8	3 (3.8)	3	2.7
No	0			0			0		
Glucose metabolism disorders (incl diabetes mellitus)									
Yes	0			2 (1.1)	3	1.2	2 (2.5)	3	2.7
No	0			0			1 (4.8)	1	3.4
Diabetes mellitus									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Type 2 diabetes mellitus									
Yes	0			1 (0.6)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Glucose tolerance impaired									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (1.3)	2	1.8
No	0			0			0		
Electrolyte and fluid balance conditions									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Dehydration									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Metabolism disorders NEC									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Hypercreatininaemia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Nervous system disorders									
Yes	7 (8.0)	10	8.5	33 (18.5)	50	20.4	3 (3.8)	3	2.7
No	1 (7.7)	1	5.5	2 (9.5)	2	6.8	3 (14.3)	3	10.3
Neurological disorders NEC									
Yes	5 (5.7)	7	5.9	21 (11.8)	32	13.0	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	1 (4.8)	1	3.4
Dizziness									
Yes	3 (3.4)	5	4.2	14 (7.9)	19	7.7	0		
No	0			0			0		
Somnolence									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (4.8)	1	3.4	0		
Hypoaesthesia									
Yes	1 (1.1)	1	0.8	3 (1.7)	4	1.6	0		
No	1 (7.7)	1	5.5	0			0		
Dizziness postural									
Yes	0			1 (0.6)	2	0.8	0		
No	0			0			0		
Dysaesthesia									
Yes	0			1 (0.6)	2	0.8	0		
No	0			0			0		
Dysgeusia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Neuralgia									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Neurological symptom									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Paraesthesia									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Taste disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Intercostal neuralgia									
Yes	0			0			1 (1.3)	1	0.9

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Sensory loss									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Headaches									
Yes	2 (2.3)	2	1.7	9 (5.1)	11	4.5	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	2 (9.5)	2	6.9
Headache									
Yes	2 (2.3)	2	1.7	9 (5.1)	11	4.5	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	2 (9.5)	2	6.9
Spinal cord and nerve root disorders									
Yes	1 (1.1)	1	0.8	3 (1.7)	3	1.2	0		
No	0			0			0		
Sciatica									
Yes	1 (1.1)	1	0.8	3 (1.7)	3	1.2	0		
No	0			0			0		
Central nervous system vascular disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Lacunar infarction									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Cranial nerve disorders (excl neoplasms)									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Parosmia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Neuromuscular disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Autonomic nervous system imbalance									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Peripheral neuropathies									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Carpal tunnel syndrome									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
General disorders and administration site conditions									
Yes	3 (3.4)	5	4.2	12 (6.7)	28	11.4	1 (1.3)	1	0.9
No	0			4 (19.0)	7	23.7	1 (4.8)	1	3.4
Administration site reactions									
Yes	0			2 (1.1)	13	5.3	0		
No	0			2 (9.5)	2	6.8	0		
Injection site erythema									
Yes	0			1 (0.6)	12	4.9	0		
No	0			1 (4.8)	1	3.4	0		
Injection site dermatitis									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Injection site discomfort									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
General system disorders NEC									
Yes	2 (2.3)	4	3.4	10 (5.6)	15	6.1	0		
No	0			1 (4.8)	3	10.2	1 (4.8)	1	3.4
Fatigue									
Yes	0			2 (1.1)	2	0.8	0		
No	0			1 (4.8)	1	3.4	0		
Feeling abnormal									
Yes	0			1 (0.6)	1	0.4	0		
No	0			1 (4.8)	1	3.4	0		
Thirst									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Malaise									
Yes	1 (1.1)	1	0.8	5 (2.8)	8	3.3	0		
No	0			0			0		
Influenza like illness									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Non-cardiac chest pain									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Oedema peripheral									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Pain									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Hangover									
Yes	1 (1.1)	3	2.5	0			0		
No	0			0			0		
Hunger									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Body temperature conditions									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	0			2 (9.5)	2	6.8	0		
Pyrexia									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	0			2 (9.5)	2	6.8	0		
Respiratory, thoracic and mediastinal disorders									
Yes	9 (10.3)	12	10.2	22 (12.4)	25	10.2	10 (12.5)	16	14.2
No	1 (7.7)	1	5.5	2 (9.5)	2	6.8	3 (14.3)	3	10.3
Respiratory tract signs and symptoms									
Yes	6 (6.9)	7	5.9	13 (7.3)	15	6.1	8 (10.0)	12	10.6
No	0			2 (9.5)	2	6.8	3 (14.3)	3	10.3
Upper respiratory tract inflammation									
Yes	5 (5.7)	6	5.1	10 (5.6)	12	4.9	7 (8.8)	11	9.8

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (4.8)	1	3.4	2 (9.5)	2	6.9
Hiccups									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Oropharyngeal pain									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			1 (4.8)	1	3.4
Rhinorrhoea									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Upper respiratory tract disorders (excl infections)									
Yes	2 (2.3)	2	1.7	7 (3.9)	7	2.9	1 (1.3)	2	1.8
No	0			0			0		
Rhinitis allergic									
Yes	1 (1.1)	1	0.8	6 (3.4)	6	2.4	1 (1.3)	2	1.8
No	0			0			0		
Epistaxis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Vasomotor rhinitis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Respiratory disorders NEC									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Cough									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Dyspnoea									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Bronchial disorders (excl neoplasms)									
Yes	2 (2.3)	2	1.7	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Asthma									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Cough variant asthma									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Injury, poisoning and procedural complications									
Yes	13 (14.9)	16	13.5	24 (13.5)	25	10.2	9 (11.3)	11	9.8
No	2 (15.4)	3	16.6	1 (4.8)	1	3.4	3 (14.3)	3	10.3
Injuries NEC									
Yes	5 (5.7)	8	6.8	16 (9.0)	17	6.9	6 (7.5)	7	6.2
No	1 (7.7)	2	11.0	1 (4.8)	1	3.4	3 (14.3)	3	10.3
Tendon rupture									
Yes	0			1 (0.6)	1	0.4	0		
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Contusion									
Yes	2 (2.3)	2	1.7	4 (2.2)	4	1.6	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Arthropod sting									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Ligament sprain									
Yes	2 (2.3)	2	1.7	3 (1.7)	3	1.2	2 (2.5)	2	1.8
No	1 (7.7)	2	11.0	0			0		
Arthropod bite									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Epicondylitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Limb injury									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Post-traumatic neck syndrome									
Yes	0			1 (0.6)	1	0.4	2 (2.5)	2	1.8
No	0			0			0		
Subcutaneous haematoma									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Tooth fracture									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Limb crushing injury									
Yes	1 (1.1)	1	0.8	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Muscle contusion									
Yes	0			0			2 (2.5)	2	1.8
No	0			0			0		
Muscle strain									
Yes	1 (1.1)	2	1.7	0			0		
No	0			0			0		
Road traffic accident									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Skin laceration									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Subdural haematoma									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Bone and joint injuries									
Yes	4 (4.6)	4	3.4	4 (2.2)	4	1.6	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Ankle fracture									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Meniscus injury									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Radius fracture									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Rib fracture									
Yes	2 (2.3)	2	1.7	1 (0.6)	1	0.4	0		
No	0			0			0		
Fracture									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Joint injury									
Yes	0			0			0		
No	1 (7.7)	1	5.5	0			0		
Injuries by physical agents									
Yes	3 (3.4)	3	2.5	2 (1.1)	2	0.8	3 (3.8)	3	2.7
No	0			0			0		
Heat stroke									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Thermal burn									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Heat illness									
Yes	1 (1.1)	1	0.8	0			2 (2.5)	2	1.8
No	0			0			0		
Medication errors and other product use errors and issues									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	0		
No	0			0			0		
Accidental overdose									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Yes	0				1	(0.6)	1	0.4	0			
No	0				0				0			
Product administration error												
Yes	1	(1.1)	1	0.8	1	(0.6)	1	0.4	0			
No	0				0				0			
Skin and subcutaneous tissue disorders												
Yes	11	(12.6)	18	15.2	23	(12.9)	29	11.8	8	(10.0)	9	8.0
No	2	(15.4)	4	22.1	1	(4.8)	1	3.4	3	(14.3)	5	17.2
Epidermal and dermal conditions												
Yes	9	(10.3)	12	10.2	16	(9.0)	18	7.3	6	(7.5)	7	6.2
No	1	(7.7)	1	5.5	1	(4.8)	1	3.4	2	(9.5)	3	10.3
Dermatitis												
Yes	0				1	(0.6)	2	0.8	0			
No	0				1	(4.8)	1	3.4	0			
Eczema												
Yes	4	(4.6)	4	3.4	4	(2.2)	4	1.6	1	(1.3)	1	0.9
No	0				0				1	(4.8)	1	3.4
Pruritus												
Yes	1	(1.1)	1	0.8	3	(1.7)	3	1.2	2	(2.5)	3	2.7
No	0				0				0			
Eczema asteatotic												
Yes	0				2	(1.1)	2	0.8	0			
No	1	(7.7)	1	5.5	0				0			
Dermatitis atopic												
Yes	0				1	(0.6)	2	0.8	0			
No	0				0				0			

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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dermatitis contact									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	3 (3.8)	3	2.7
No	0			0			0		
Dyshidrotic eczema									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Erythema									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Rash									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Stasis dermatitis									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Drug eruption									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Dry skin									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Pain of skin									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Rash pruritic									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Seborrhoeic dermatitis									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Xanthelasma									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Skin appendage conditions									
Yes	2 (2.3)	2	1.7	7 (3.9)	7	2.9	1 (1.3)	1	0.9
No	2 (15.4)	2	11.0	0			1 (4.8)	1	3.4
Alopecia									
Yes	2 (2.3)	2	1.7	2 (1.1)	2	0.8	0		
No	0			0			0		
Alopecia areata									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Acne									
Yes	0			1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		
Ingrowing nail									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Miliaria									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			1 (4.8)	1	3.4
Angioedema and urticaria									
Yes	3 (3.4)	4	3.4	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			1 (4.8)	1	3.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urticaria									
Yes	3 (3.4)	4	3.4	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			1 (4.8)	1	3.4
Cornification and dystrophic skin disorders									
Yes	0			2 (1.1)	2	0.8	0		
No	1 (7.7)	1	5.5	0			0		
Hyperkeratosis									
Yes	0			1 (0.6)	1	0.4	0		
No	1 (7.7)	1	5.5	0			0		
Xeroderma									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Eye disorders									
Yes	6 (6.9)	7	5.9	17 (9.6)	19	7.7	6 (7.5)	7	6.2
No	0			0			1 (4.8)	1	3.4
Retina, choroid and vitreous haemorrhages and vascular disorders									
Yes	2 (2.3)	3	2.5	5 (2.8)	5	2.0	2 (2.5)	2	1.8
No	0			0			0		
Diabetic retinopathy									
Yes	1 (1.1)	2	1.7	3 (1.7)	3	1.2	2 (2.5)	2	1.8
No	0			0			0		
Retinal exudates									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retinal haemorrhage									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Retinopathy									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Vision disorders									
Yes	0			4 (2.2)	4	1.6	0		
No	0			0			0		
Amblyopia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Optic nerve disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Presbyopia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Visual acuity reduced									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Anterior eye structural change, deposit and degeneration									
Yes	0			3 (1.7)	3	1.2	1 (1.3)	1	0.9
No	0			0			0		
Cataract									
Yes	0			3 (1.7)	3	1.2	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Ocular infections, irritations and inflammations									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Conjunctivitis allergic									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Ocular hyperaemia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Eye disorders NEC									
Yes	1 (1.1)	1	0.8	1 (0.6)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Lacrimal disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Lacrimation increased									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Dry eye									
Yes	1 (1.1)	1	0.8	0			1 (1.3)	1	0.9
No	0			0			0		
Glaucoma and ocular hypertension									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Glaucoma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Open angle glaucoma									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Ocular haemorrhages and vascular disorders NEC									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			0			0		
Optic disc haemorrhage									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Conjunctival haemorrhage									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Yes	2 (2.3)	2	1.7	1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Retinal tear									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Macular fibrosis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Rhegmatogenous retinal detachment									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (4.8)	1	3.4
Reproductive system and breast disorders									
Yes	2 (2.3)	3	2.5	8 (4.5)	8	3.3	0		
No	1 (7.7)	1	5.5	1 (4.8)	2	6.8	0		
Male reproductive tract infections and inflammations									
Yes	0			0			0		
No	0			1 (4.8)	2	6.8	0		
Prostatitis									
Yes	0			0			0		
No	0			1 (4.8)	2	6.8	0		
Menstrual cycle and uterine bleeding disorders									
Yes	0			4 (2.2)	4	1.6	0		
No	0			0			0		
Dysmenorrhoea									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Menstrual disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Menstruation irregular									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Prostatic disorders (excl infections and inflammations)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	0		
No	0			0			0		
Benign prostatic hyperplasia									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	0		
No	0			0			0		
Breast disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Breast calcifications									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Menopause related conditions									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Menopausal symptoms									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Uterine, pelvic and broad ligament disorders									
Yes	1 (1.1)	2	1.7	0			0		
No	1 (7.7)	1	5.5	0			0		
Endometrial hyperplasia									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Endometriosis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Uterine haemorrhage									
Yes	0			0			0		
No	1 (7.7)	1	5.5	0			0		
Investigations									
Yes	12 (13.8)	14	11.9	16 (9.0)	20	8.1	7 (8.8)	9	8.0
No	1 (7.7)	2	11.0	0			2 (9.5)	2	6.9
Enzyme investigations NEC									
Yes	3 (3.4)	3	2.5	6 (3.4)	7	2.9	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	0			0		
Blood creatine phosphokinase increased									
Yes	3 (3.4)	3	2.5	6 (3.4)	7	2.9	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	0			0		
Gastrointestinal investigations									
Yes	4 (4.6)	4	3.4	4 (2.2)	5	2.0	0		
No	1 (7.7)	1	5.5	0			0		
Lipase increased									
Yes	2 (2.3)	2	1.7	4 (2.2)	4	1.6	0		
No	1 (7.7)	1	5.5	0			0		
Amylase increased									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Occult blood positive									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cardiac and vascular investigations (excl enzyme tests)									
Yes	2 (2.3)	2	1.7	3 (1.7)	3	1.2	0		
No	0			0			0		
Blood pressure decreased									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Electrocardiogram QRS complex prolonged									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Electrocardiogram QT prolonged									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Hepatobiliary investigations									
Yes	0			2 (1.1)	2	0.8	4 (5.0)	4	3.5
No	0			0			1 (4.8)	1	3.4
Aspartate aminotransferase increased									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Liver function test increased									
Yes	0			1 (0.6)	1	0.4	2 (2.5)	2	1.8
No	0			0			0		
Alanine aminotransferase increased									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			1 (4.8)	1	3.4
Blood bilirubin increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Endocrine investigations (incl sex hormones)									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Blood thyroid stimulating hormone decreased									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Haematology investigations (incl blood groups)									
Yes	1 (1.1)	2	1.7	1 (0.6)	1	0.4	0		
No	0			0			0		
Haemoglobin decreased									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Lymphocyte count decreased									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
White blood cell count increased									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Physical examination and organ system status topics									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Weight decreased									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Lipid analyses									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Blood triglycerides increased									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Metabolic, nutritional and blood gas investigations									
Yes	0			0			2 (2.5)	2	1.8
No	0			0			0		
Blood uric acid increased									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Glycosylated haemoglobin increased									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Protein and chemistry analyses NEC									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			1 (4.8)	1	3.4
C-reactive protein increased									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			1 (4.8)	1	3.4
Water, electrolyte and mineral investigations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Blood potassium increased									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Hepatobiliary disorders									
Yes	2 (2.3)	2	1.7	4 (2.2)	4	1.6	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Hepatic and hepatobiliary disorders									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Hepatic cyst									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Hepatic function abnormal									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Alcoholic liver disease									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Hepatic steatosis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Gallbladder disorders									
Yes	1 (1.1)	1	0.8	3 (1.7)	3	1.2	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cholelithiasis									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Gallbladder polyp									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Hyperplastic cholecystopathy									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Renal and urinary disorders									
Yes	4 (4.6)	5	4.2	4 (2.2)	4	1.6	4 (5.0)	6	5.3
No	1 (7.7)	1	5.5	1 (4.8)	1	3.4	1 (4.8)	1	3.4
Renal disorders (excl nephropathies)									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Renal cyst									
Yes	0			0			1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Azotaemia									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Urolithiases									
Yes	3 (3.4)	3	2.5	2 (1.1)	2	0.8	2 (2.5)	4	3.5
No	0			0			1 (4.8)	1	3.4
Ureterolithiasis									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	2 (2.5)	4	3.5
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Calculus urinary									
Yes	2 (2.3)	2	1.7	0			0		
No	0			0			1 (4.8)	1	3.4
Urinary tract signs and symptoms									
Yes	1 (1.1)	2	1.7	1 (0.6)	1	0.4	0		
No	0			0			0		
Hyperuricosuria									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Nocturia									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Proteinuria									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Nephropathies									
Yes	0			0			1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Diabetic nephropathy									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Nephropathy toxic									
Yes	0			0			0		
No	1 (7.7)	1	5.5	0			0		
Cardiac disorders									
Yes	2 (2.3)	2	1.7	3 (1.7)	3	1.2	2 (2.5)	2	1.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (4.8)	1	3.4	1 (4.8)	1	3.4
Cardiac arrhythmias									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	2 (2.5)	2	1.8
No	0			1 (4.8)	1	3.4	0		
Tachycardia									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Ventricular extrasystoles									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			0		
Arrhythmia									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Atrial fibrillation									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Cardiac disorders, signs and symptoms NEC									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Palpitations									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Coronary artery disorders									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Acute myocardial infarction									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Vascular disorders									
Yes	1 (1.1)	1	0.8	11 (6.2)	11	4.5	3 (3.8)	3	2.7
No	1 (7.7)	1	5.5	0			1 (4.8)	1	3.4
Decreased and nonspecific blood pressure disorders and shock									
Yes	0			5 (2.8)	5	2.0	0		
No	0			0			0		
Orthostatic hypotension									
Yes	0			3 (1.7)	3	1.2	0		
No	0			0			0		
Hypotension									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Vascular hypertensive disorders									
Yes	0			4 (2.2)	4	1.6	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	0			1 (4.8)	1	3.4
Hypertension									
Yes	0			4 (2.2)	4	1.6	2 (2.5)	2	1.8
No	1 (7.7)	1	5.5	0			1 (4.8)	1	3.4
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Yes	0			2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Arteriosclerosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	0			0			0		
Embolism and thrombosis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Venous thrombosis limb									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Yes	2 (2.3)	2	1.7	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	0			1 (4.8)	1	3.4	0		
Gastrointestinal neoplasms benign									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Intraductal papillary mucinous neoplasm									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Reproductive neoplasms female benign									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Uterine leiomyoma									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hepatobiliary neoplasms malignant and unspecified									
Yes	1	(1.1)	1 0.8	0			0		
No	0			0			0		
Bile duct adenocarcinoma									
Yes	1	(1.1)	1 0.8	0			0		
No	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
Yes	1	(1.1)	1 0.8	0			0		
No	0			0			0		
Clear cell renal cell carcinoma									
Yes	1	(1.1)	1 0.8	0			0		
No	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Yes	0			0			1	(1.3)	1 0.9
No	0			0			0		
Lung neoplasm malignant									
Yes	0			0			1	(1.3)	1 0.9
No	0			0			0		
Endocrine disorders									
Yes	0			0			0		
No	0			1	(4.8)	1 3.4	0		
Thyroid gland disorders									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (4.8)	1	3.4	0		
Hyperthyroidism									
Yes	0			0			0		
No	0			1 (4.8)	1	3.4	0		
Psychiatric disorders									
Yes	4 (4.6)	4	3.4	6 (3.4)	6	2.4	0		
No	0			0			1 (4.8)	1	3.4
Sleep disorders and disturbances									
Yes	3 (3.4)	3	2.5	4 (2.2)	4	1.6	0		
No	0			0			0		
Insomnia									
Yes	3 (3.4)	3	2.5	4 (2.2)	4	1.6	0		
No	0			0			0		
Depressed mood disorders and disturbances									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Depression									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Mood disorders and disturbances NEC									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			1 (4.8)	1	3.4
Emotional disorder									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Listless									
Yes	0			0			0		
No	0			0			1 (4.8)	1	3.4
Adjustment disorders (incl subtypes)									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Adjustment disorder									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Ear and labyrinth disorders									
Yes	3 (3.4)	3	2.5	3 (1.7)	3	1.2	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Hearing disorders									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Deafness									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Deafness neurosensory									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Inner ear and VIIIth cranial nerve disorders									
Yes	3 (3.4)	3	2.5	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Vertigo									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	2 (2.3)	2	1.7	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Tinnitus									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Blood and lymphatic system disorders									
Yes	1 (1.1)	1	0.8	2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Anaemias nonhaemolytic and marrow depression									
Yes	0			2 (1.1)	2	0.8	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Iron deficiency anaemia									
Yes	0			2 (1.1)	2	0.8	0		
No	1 (7.7)	1	5.5	0			0		
Anaemia									
Yes	0			0			1 (1.3)	1	0.9
No	0			0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Lymphadenitis									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Congenital, familial and genetic disorders									
Yes	0			2 (1.1)	2	0.8	0		
No	0			0			0		
Gastrointestinal tract disorders congenital									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Diverticulitis Meckel's									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Skin and subcutaneous tissue disorders congenital									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Birth mark									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Immune system disorders									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Allergic conditions									
Yes	1 (1.1)	1	0.8	1 (0.6)	1	0.4	1 (1.3)	1	0.9
No	1 (7.7)	1	5.5	0			0		
Seasonal allergy									
Yes	0			1 (0.6)	1	0.4	1 (1.3)	1	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by dyslipidaemia at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (7.7)	1	5.5	0			0		
Food allergy									
Yes	1 (1.1)	1	0.8	0			0		
No	0			0			0		
Surgical and medical procedures									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Gastrointestinal therapeutic procedures									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		
Large intestinal polypectomy									
Yes	0			1 (0.6)	1	0.4	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

37 Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
Yes	472	631.8			234	304.3		
No	834	1074.3			421	525.3		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Events								
Yes	427	(90.5)	3223	510.2	205	(87.6)	1170	384.5
No	744	(89.2)	6435	599.0	361	(85.7)	2132	405.9
Serious								
Yes								
Yes	59	(12.5)	77	12.2	19	(8.1)	27	8.9
No	69	(8.3)	87	8.1	23	(5.5)	26	5.0
No								
Yes	425	(90.0)	3146	498.0	201	(85.9)	1143	375.6
No	744	(89.2)	6348	590.9	359	(85.3)	2106	401.0
Severity								
Severe								
Yes	45	(9.5)	79	12.5	16	(6.8)	29	9.5
No	98	(11.8)	163	15.2	28	(6.7)	39	7.4
Moderate								
Yes	266	(56.4)	1000	158.3	118	(50.4)	361	118.6
No	457	(54.8)	1612	150.0	193	(45.8)	502	95.6
Mild								
Yes	383	(81.1)	2144	339.4	178	(76.1)	780	256.3
No	696	(83.5)	4660	433.8	329	(78.1)	1591	302.9

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Relationship to trial product								
Missing								
Yes	10	(2.1)	11	1.7	4	(1.7)	4	1.3
No	14	(1.7)	19	1.8	3	(0.7)	4	0.8
Probable								
Yes	191	(40.5)	670	106.1	43	(18.4)	82	26.9
No	380	(45.6)	1478	137.6	104	(24.7)	248	47.2
Possible								
Yes	242	(51.3)	857	135.7	73	(31.2)	145	47.6
No	484	(58.0)	1843	171.5	150	(35.6)	410	78.1
Unlikely								
Yes	387	(82.0)	1685	266.7	194	(82.9)	939	308.6
No	645	(77.3)	3095	288.1	342	(81.2)	1470	279.9
Outcome								
Fatal								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Recovered								
Yes	417	(88.3)	2763	437.4	194	(82.9)	924	303.6
No	723	(86.7)	5676	528.3	351	(83.4)	1786	340.0
Recovering								
Yes	24	(5.1)	38	6.0	9	(3.8)	12	3.9
No	35	(4.2)	53	4.9	16	(3.8)	25	4.8
Recovered With Sequelae								
Yes	4	(0.8)	8	1.3	3	(1.3)	4	1.3
No	7	(0.8)	11	1.0	1	(0.2)	1	0.2
Not Recovered								
Yes	193	(40.9)	412	65.2	105	(44.9)	229	75.3

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Outcome								
Not Recovered								
No	320	(38.4)	694	64.6	160	(38.0)	319	60.7
Unknown								
Yes	1	(0.2)	2	0.3	1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Leading to								
Permanent treatment discontinuation								
Yes	28	(5.9)	38	6.0	4	(1.7)	4	1.3
No	64	(7.7)	85	7.9	16	(3.8)	19	3.6
Temporary interruption of trial product								
Yes	42	(8.9)	94	14.9	9	(3.8)	13	4.3
No	84	(10.1)	171	15.9	17	(4.0)	31	5.9
Dose reduction of trial product								
Yes	42	(8.9)	71	11.2	2	(0.9)	6	2.0
No	82	(9.8)	154	14.3	2	(0.5)	3	0.6

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

38 Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
Yes	472	631.8			234	304.3		
No	834	1074.3			421	525.3		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Adverse events								
Yes	427	(90.5)	3223	510.2	205	(87.6)	1170	384.5
No	744	(89.2)	6435	599.0	361	(85.7)	2132	405.9
Gastrointestinal disorders								
Yes	327	(69.3)	1381	218.6	104	(44.4)	215	70.7
No	642	(77.0)	2928	272.5	210	(49.9)	524	99.8
Gastrointestinal signs and symptoms								
Yes	265	(56.1)	864	136.8	60	(25.6)	105	34.5
No	559	(67.0)	1850	172.2	141	(33.5)	290	55.2
Nausea								
Yes	180	(38.1)	356	56.4	31	(13.2)	35	11.5
No	397	(47.6)	712	66.3	83	(19.7)	111	21.1
Vomiting								
Yes	85	(18.0)	185	29.3	12	(5.1)	13	4.3
No	239	(28.7)	451	42.0	31	(7.4)	39	7.4
Dyspepsia								
Yes	44	(9.3)	57	9.0	7	(3.0)	9	3.0
No	91	(10.9)	122	11.4	16	(3.8)	21	4.0
Abdominal pain								
Yes	38	(8.1)	57	9.0	7	(3.0)	8	2.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	92 (11.0)	118	11.0	29 (6.9)	33	6.3
Abdominal pain upper						
Yes	35 (7.4)	52	8.2	9 (3.8)	10	3.3
No	90 (10.8)	124	11.5	26 (6.2)	27	5.1
Eructation						
Yes	33 (7.0)	37	5.9	2 (0.9)	2	0.7
No	79 (9.5)	102	9.5	1 (0.2)	1	0.2
Abdominal distension						
Yes	30 (6.4)	54	8.5	7 (3.0)	10	3.3
No	66 (7.9)	81	7.5	24 (5.7)	32	6.1
Flatulence						
Yes	23 (4.9)	27	4.3	10 (4.3)	10	3.3
No	42 (5.0)	57	5.3	11 (2.6)	12	2.3
Abdominal discomfort						
Yes	20 (4.2)	31	4.9	2 (0.9)	2	0.7
No	36 (4.3)	48	4.5	7 (1.7)	7	1.3
Abdominal pain lower						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	11 (1.3)	11	1.0	3 (0.7)	3	0.6
Epigastric discomfort						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Gastrointestinal pain						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	3	0.3	0		
Regurgitation						
Yes	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	3	0.3	0		
Faeces soft						
Yes	0			3 (1.3)	3	1.0
No	3 (0.4)	4	0.4	2 (0.5)	2	0.4
Dysphagia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Faeces discoloured						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Retching						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Breath odour						
Yes	0			0		
No	2 (0.2)	3	0.3	1 (0.2)	1	0.2
Gastrointestinal sounds abnormal						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Faeces hard						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Abdominal tenderness						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Abnormal faeces						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Aerophagia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Oesophageal pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal motility and defaecation conditions						
Yes	215 (45.6)	420	66.5	51 (21.8)	65	21.4
No	411 (49.3)	851	79.2	115 (27.3)	174	33.1
Diarrhoea						
Yes	136 (28.8)	238	37.7	33 (14.1)	39	12.8
No	276 (33.1)	528	49.1	71 (16.9)	99	18.8
Constipation						
Yes	109 (23.1)	132	20.9	14 (6.0)	17	5.6
No	197 (23.6)	258	24.0	48 (11.4)	56	10.7
Gastrooesophageal reflux disease						
Yes	37 (7.8)	42	6.6	7 (3.0)	7	2.3
No	45 (5.4)	50	4.7	13 (3.1)	14	2.7
Irritable bowel syndrome						
Yes	1 (0.2)	2	0.3	0		
No	5 (0.6)	5	0.5	1 (0.2)	2	0.4
Frequent bowel movements						
Yes	0			2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Dyschezia						

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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Impaired gastric emptying						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Bowel movement irregularity						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Gastrointestinal hypermotility						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Oesophageal achalasia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Change of bowel habit						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Defaecation urgency						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Gastrointestinal motility disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Infrequent bowel movements						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions						
Yes	24 (5.1)	25	4.0	5 (2.1)	5	1.6
No	47 (5.6)	69	6.4	7 (1.7)	8	1.5
Gastritis						
Yes	15 (3.2)	16	2.5	2 (0.9)	2	0.7
No	35 (4.2)	51	4.7	4 (1.0)	5	1.0
Colitis						
Yes	4 (0.8)	4	0.6	0		
No	3 (0.4)	5	0.5	1 (0.2)	1	0.2
Reflux gastritis						
Yes	0			1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	0		
Oesophagitis						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Enteritis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Chronic gastritis						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Duodenitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Gastrointestinal inflammation						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	0		
Colitis ischaemic						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Gastroenteritis eosinophilic						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Crohn's disease						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eosinophilic oesophagitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Epiploic appendagitis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Inflammatory bowel disease						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Gastrointestinal conditions NEC						
Yes	15 (3.2)	18	2.8	3 (1.3)	3	1.0
No	33 (4.0)	49	4.6	9 (2.1)	13	2.5
Hyperchlorhydria						
Yes	8 (1.7)	11	1.7	1 (0.4)	1	0.3
No	12 (1.4)	26	2.4	2 (0.5)	4	0.8
Food poisoning						
Yes	5 (1.1)	5	0.8	1 (0.4)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	13 (1.6)	13	1.2	3 (0.7)	5	1.0
Gastrointestinal disorder						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	6	0.6	4 (1.0)	4	0.8
Anal fistula						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Gastric mucosal hypertrophy						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Barrett's oesophagus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Functional gastrointestinal disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Dental and gingival conditions						
Yes	11 (2.3)	14	2.2	13 (5.6)	13	4.3
No	16 (1.9)	18	1.7	16 (3.8)	19	3.6
Toothache						
Yes	6 (1.3)	8	1.3	6 (2.6)	6	2.0
No	11 (1.3)	12	1.1	11 (2.6)	12	2.3
Dental caries						
Yes	2 (0.4)	3	0.5	7 (3.0)	7	2.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Gingival disorder						
Yes	1 (0.2)	1	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Noninfective gingivitis						
Yes	1	(0.2)	1 0.2	0		
No	0			1	(0.2)	1 0.2
Periodontal disease						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Gingival bleeding						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Gingival pain						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Tooth impacted						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Tooth loss						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Dental necrosis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Dental pulp disorder						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Tooth disorder						
Yes	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Gastrointestinal vascular conditions						
Yes	9 (1.9)	9	1.4	5 (2.1)	5	1.6
No	19 (2.3)	21	2.0	0		
Haemorrhoids						
Yes	9 (1.9)	9	1.4	3 (1.3)	3	1.0
No	17 (2.0)	18	1.7	0		
Haemorrhoidal haemorrhage						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	2	0.2	0		
Haemorrhoids thrombosed						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Salivary gland conditions						
Yes	9 (1.9)	9	1.4	3 (1.3)	4	1.3
No	18 (2.2)	18	1.7	5 (1.2)	5	1.0
Dry mouth						
Yes	8 (1.7)	8	1.3	3 (1.3)	4	1.3
No	17 (2.0)	17	1.6	4 (1.0)	4	0.8
Salivary gland cyst						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Salivary gland calculus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Salivary gland enlargement						
Yes	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Gastrointestinal haemorrhages NEC						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	13 (1.6)	14	1.3	4 (1.0)	5	1.0
Haematochezia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	2 (0.5)	3	0.6
Rectal haemorrhage						
Yes	0			0		
No	7 (0.8)	7	0.7	1 (0.2)	1	0.2
Lower gastrointestinal haemorrhage						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Haematemesis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Melaena						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Upper gastrointestinal haemorrhage						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Benign neoplasms gastrointestinal						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Large intestine polyp						
Yes	4 (0.8)	4	0.6	2 (0.9)	2	0.7

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Gastric polyps						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Abdominal hernias and other abdominal wall conditions						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	5 (0.6)	6	0.6	1 (0.2)	1	0.2
Hiatus hernia						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	4 (0.5)	5	0.5	0		
Abdominal hernia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Umbilical hernia						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Oral soft tissue conditions						
Yes	3 (0.6)	3	0.5	3 (1.3)	3	1.0
No	5 (0.6)	6	0.6	3 (0.7)	3	0.6
Lip swelling						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Odynophagia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Aphthous ulcer						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cheilitis						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Lip disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Mouth ulceration						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Paraesthesia oral						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Stomatitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Oral mucosal eruption						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Diverticular disorders						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Diverticulum						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Anal and rectal conditions NEC						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	6 (0.7)	8	0.7	0		
Anal fissure						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Proctalgia						
Yes	0			0		
No	2 (0.2)	3	0.3	0		
Anal pruritus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Anorectal discomfort						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Rectal fissure						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal ulceration and perforation						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	0		
Oesophageal ulcer						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Duodenal ulcer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastric ulcer						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Large intestine perforation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Peptic ulcer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal stenosis and obstruction						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Volvulus						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Ileus						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Oesophageal stenosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Intestinal obstruction						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Exocrine pancreas conditions						
Yes	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	1	(0.1)	1	<0.1	0			
Pancreatitis acute								
Yes	1	(0.2)	1	0.2	0			
No	1	(0.1)	1	<0.1	0			
Malabsorption conditions								
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Coeliac disease								
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Peritoneal and retroperitoneal conditions								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Pneumoperitoneum								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Tongue conditions								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Glossodynia								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Infections and infestations								
Yes	255	(54.0)	542	85.8	131	(56.0)	293	96.3
No	459	(55.0)	1073	99.9	241	(57.2)	509	96.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Infections - pathogen unspecified						
Yes	226 (47.9)	426	67.4	110 (47.0)	221	72.6
No	400 (48.0)	821	76.4	204 (48.5)	389	74.1
Nasopharyngitis						
Yes	99 (21.0)	153	24.2	40 (17.1)	62	20.4
No	182 (21.8)	327	30.4	93 (22.1)	154	29.3
Upper respiratory tract infection						
Yes	39 (8.3)	60	9.5	29 (12.4)	48	15.8
No	75 (9.0)	98	9.1	51 (12.1)	68	12.9
Gastroenteritis						
Yes	29 (6.1)	34	5.4	12 (5.1)	18	5.9
No	56 (6.7)	70	6.5	18 (4.3)	20	3.8
Sinusitis						
Yes	27 (5.7)	34	5.4	16 (6.8)	18	5.9
No	44 (5.3)	50	4.7	20 (4.8)	22	4.2
Urinary tract infection						
Yes	24 (5.1)	28	4.4	12 (5.1)	15	4.9
No	44 (5.3)	55	5.1	16 (3.8)	19	3.6
Bronchitis						
Yes	20 (4.2)	24	3.8	9 (3.8)	9	3.0
No	27 (3.2)	28	2.6	16 (3.8)	19	3.6
Rhinitis						
Yes	8 (1.7)	12	1.9	3 (1.3)	5	1.6
No	11 (1.3)	13	1.2	6 (1.4)	9	1.7
Cystitis						
Yes	7 (1.5)	7	1.1	0		
No	12 (1.4)	14	1.3	3 (0.7)	3	0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Laryngitis						
Yes	3 (0.6)	3	0.5	0		
No	11 (1.3)	11	1.0	4 (1.0)	5	1.0
Pharyngitis						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	9 (1.1)	9	0.8	6 (1.4)	6	1.1
Pneumonia						
Yes	6 (1.3)	9	1.4	4 (1.7)	4	1.3
No	5 (0.6)	5	0.5	4 (1.0)	4	0.8
Tonsillitis						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	10 (1.2)	13	1.2	7 (1.7)	9	1.7
Acute sinusitis						
Yes	3 (0.6)	3	0.5	5 (2.1)	6	2.0
No	8 (1.0)	9	0.8	3 (0.7)	3	0.6
Tooth infection						
Yes	3 (0.6)	3	0.5	0		
No	8 (1.0)	9	0.8	5 (1.2)	5	1.0
Ear infection						
Yes	5 (1.1)	6	0.9	1 (0.4)	1	0.3
No	4 (0.5)	5	0.5	2 (0.5)	2	0.4
Vaginal infection						
Yes	2 (0.4)	2	0.3	0		
No	9 (1.1)	11	1.0	0		
Lower respiratory tract infection						
Yes	2 (0.4)	3	0.5	5 (2.1)	8	2.6
No	7 (0.8)	7	0.7	7 (1.7)	8	1.5

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tooth abscess						
Yes	1 (0.2)	1	0.2	3 (1.3)	3	1.0
No	7 (0.8)	7	0.7	5 (1.2)	6	1.1
Conjunctivitis						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Pulpitis dental						
Yes	4 (0.8)	4	0.6	0		
No	1 (0.1)	1	<0.1	0		
Otitis media						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Appendicitis						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Gastrointestinal infection						
Yes	2 (0.4)	3	0.5	2 (0.9)	2	0.7
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Eye infection						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	4	0.4	0		
Folliculitis						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Chronic sinusitis						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gingivitis						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Hordeolum						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Infected bite						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Kidney infection						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Pharyngotonsillitis						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	2	0.4
Breast abscess						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Pyelonephritis						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Subcutaneous abscess						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Abdominal wall abscess						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abscess						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Diarrhoea infectious						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Localised infection						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Atypical pneumonia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Infection						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Omphalitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Otitis externa						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Periodontitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Postoperative wound infection						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abscess limb						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Device related infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Diverticulitis						
Yes	1 (0.2)	1	0.2	0		
No	0			2 (0.5)	2	0.4
Epididymitis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Large intestine infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Oral infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Osteomyelitis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Parasitic gastroenteritis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Prostate infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Purulence						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Respiratory tract infection						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Abdominal abscess						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Appendicitis perforated						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Bartholinitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Carbuncle						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Endometritis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eyelid infection						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Fracture infection						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Groin abscess						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Haematoma infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Mastitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Nail infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Oophoritis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Paronychia						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Parotitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Perirectal abscess						
Yes	0			0		
No	1	(0.1)	2 0.2	0		
Peritonitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Salpingitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Sepsis syndrome						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin infection						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Arthritis infective						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Cervicitis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Empyema						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Gastric infection						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Infected dermal cyst						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Lymphangitis						
Yes	0			0		
No	0			1 (0.2)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Neutropenic sepsis								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Otitis media acute								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Peritonsillar abscess								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Peritonsillitis								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Root canal infection								
Yes	0				1	(0.4)	1	0.3
No	0				1	(0.2)	1	0.2
Septic shock								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Tracheitis								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Wound infection								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Viral infectious disorders								
Yes	58	(12.3)	76	12.0	36	(15.4)	48	15.8
No	136	(16.3)	172	16.0	67	(15.9)	88	16.8

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Influenza						
Yes	26 (5.5)	31	4.9	20 (8.5)	26	8.5
No	63 (7.6)	81	7.5	43 (10.2)	53	10.1
Gastroenteritis viral						
Yes	13 (2.8)	13	2.1	4 (1.7)	4	1.3
No	29 (3.5)	31	2.9	10 (2.4)	11	2.1
Viral infection						
Yes	7 (1.5)	12	1.9	3 (1.3)	3	1.0
No	7 (0.8)	8	0.7	5 (1.2)	5	1.0
Herpes zoster						
Yes	4 (0.8)	5	0.8	5 (2.1)	5	1.6
No	8 (1.0)	8	0.7	6 (1.4)	6	1.1
Gastrointestinal viral infection						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	6 (0.7)	7	0.7	0		
Viral upper respiratory tract infection						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Ear infection viral						
Yes	3 (0.6)	3	0.5	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Gastroenteritis norovirus						
Yes	0			0		
No	5 (0.6)	6	0.6	0		
Herpes simplex						
Yes	1 (0.2)	1	0.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Oral herpes						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Dengue fever						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Viral pharyngitis						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Herpes virus infection						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Respiratory tract infection viral						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Gastroenteritis astroviral						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Genital herpes zoster						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Infectious mononucleosis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Papilloma viral infection						
Yes	1 (0.2)	1	0.2	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Parainfluenzae virus infection						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Respiratory syncytial virus infection						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Chronic hepatitis B						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Cytomegalovirus infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Hepatitis E						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Oral viral infection						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Varicella						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Vestibular neuronitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Viral sinusitis						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Bronchitis viral						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Conjunctivitis viral						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hand-foot-and-mouth disease						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Meningitis viral						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Viral rhinitis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bacterial infectious disorders						
Yes	19 (4.0)	20	3.2	14 (6.0)	17	5.6
No	38 (4.6)	43	4.0	13 (3.1)	14	2.7
Pharyngitis streptococcal						
Yes	5 (1.1)	5	0.8	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	5 (1.2)	5	1.0
Cellulitis						
Yes	5 (1.1)	5	0.8	6 (2.6)	6	2.0
No	4 (0.5)	4	0.4	1 (0.2)	2	0.4
Helicobacter infection						

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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Ear infection bacterial						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Bacterial vaginosis						
Yes	0			1 (0.4)	1	0.3
No	5 (0.6)	8	0.7	1 (0.2)	1	0.2
Staphylococcal infection						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Furuncle						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	3	0.3	0		
Erysipelas						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Helicobacter gastritis						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Genital infection bacterial						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Salmonellosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Sinusitis bacterial						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Skin bacterial infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bacterial colitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Bacterial vulvovaginitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lyme disease						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pharyngitis bacterial						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Syphilis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tonsillitis bacterial						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Typhoid fever						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Bacteriuria						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Gastric ulcer helicobacter						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Listeriosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Staphylococcal sepsis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Streptococcal urinary tract infection						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Upper respiratory tract infection bacterial						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Fungal infectious disorders						
Yes	17 (3.6)	19	3.0	7 (3.0)	7	2.3
No	28 (3.4)	34	3.2	15 (3.6)	17	3.2
Vulvovaginal mycotic infection						
Yes	5 (1.1)	6	0.9	1 (0.4)	1	0.3
No	6 (0.7)	7	0.7	1 (0.2)	1	0.2
Fungal infection						
Yes	2 (0.4)	2	0.3	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	8 (1.0)	9	0.8	5 (1.2)	5	1.0
Tinea pedis						
Yes	1 (0.2)	1	0.2	0		
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Vulvovaginal candidiasis						
Yes	0			1 (0.4)	1	0.3
No	5 (0.6)	8	0.7	2 (0.5)	2	0.4
Body tinea						
Yes	2 (0.4)	2	0.3	0		
No	0			1 (0.2)	1	0.2
Onychomycosis						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	0			3 (0.7)	4	0.8
Dermatophytosis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Fungal skin infection						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Skin candida						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Candida infection						
Yes	1 (0.2)	1	0.2	0		
No	0			2 (0.5)	2	0.4
Tinea capitis						
Yes	1 (0.2)	1	0.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Tinea cruris						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Dermatophytosis of nail						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tinea infection						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Oral candidiasis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Otitis externa fungal						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Protozoal infectious disorders						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Trichomoniasis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Toxoplasmosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Chlamydial infectious disorders						
Yes	1 (0.2)	1	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Chlamydial infection						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Ectoparasitic disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Acarodermatitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nervous system disorders						
Yes	140 (29.7)	242	38.3	47 (20.1)	66	21.7
No	251 (30.1)	516	48.0	94 (22.3)	156	29.7
Headaches						
Yes	72 (15.3)	108	17.1	23 (9.8)	29	9.5
No	157 (18.8)	343	31.9	66 (15.7)	89	16.9
Headache						
Yes	66 (14.0)	100	15.8	22 (9.4)	28	9.2
No	132 (15.8)	287	26.7	58 (13.8)	76	14.5
Migraine						
Yes	3 (0.6)	3	0.5	0		
No	29 (3.5)	49	4.6	9 (2.1)	11	2.1
Sinus headache						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Tension headache						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Yes	1	(0.2)	1	0.2	0			
No	3	(0.4)	3	0.3	1	(0.2)	1	0.2
Migraine with aura								
Yes	1	(0.2)	1	0.2	0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Occipital neuralgia								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Neurological disorders NEC								
Yes	74	(15.7)	103	16.3	21	(9.0)	23	7.6
No	107	(12.8)	145	13.5	26	(6.2)	45	8.6
Dizziness								
Yes	44	(9.3)	58	9.2	7	(3.0)	7	2.3
No	54	(6.5)	72	6.7	16	(3.8)	28	5.3
Dysgeusia								
Yes	6	(1.3)	7	1.1	3	(1.3)	3	1.0
No	12	(1.4)	17	1.6	1	(0.2)	8	1.5
Paraesthesia								
Yes	4	(0.8)	6	0.9	2	(0.9)	2	0.7
No	9	(1.1)	11	1.0	3	(0.7)	3	0.6
Syncope								
Yes	6	(1.3)	6	0.9	1	(0.4)	1	0.3
No	5	(0.6)	5	0.5	1	(0.2)	1	0.2
Taste disorder								
Yes	3	(0.6)	4	0.6	1	(0.4)	1	0.3
No	6	(0.7)	7	0.7	0			
Lethargy								

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Somnolence						
Yes	3 (0.6)	4	0.6	1 (0.4)	1	0.3
No	4 (0.5)	5	0.5	0		
Hypoaesthesia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Hyperaesthesia						
Yes	3 (0.6)	5	0.8	0		
No	1 (0.1)	1	<0.1	0		
Neuralgia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Dizziness postural						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Burning sensation						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Allodynia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Balance disorder						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Presyncope						

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Ageusia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Dysaesthesia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Loss of consciousness						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Restless legs syndrome						
Yes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Vertigo CNS origin						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Aphasia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Dysarthria						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hyporeflexia						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Sensory disturbance						

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Sensory loss						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Spinal cord and nerve root disorders						
Yes	12 (2.5)	12	1.9	7 (3.0)	7	2.3
No	8 (1.0)	10	0.9	7 (1.7)	7	1.3
Sciatica						
Yes	7 (1.5)	7	1.1	5 (2.1)	5	1.6
No	7 (0.8)	9	0.8	3 (0.7)	3	0.6
Cervicobrachial syndrome						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Cervical radiculopathy						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Lumbar radiculopathy						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Lumbosacral radiculopathy						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Spinal cord compression						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Peripheral neuropathies						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	8 (1.7)	9	1.4	4 (1.7)	5	1.6
No	4 (0.5)	4	0.4	4 (1.0)	4	0.8
Carpal tunnel syndrome						
Yes	3 (0.6)	4	0.6	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Neuropathy peripheral						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Nerve compression						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Peripheral sensory neuropathy						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Peroneal nerve palsy						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Radial nerve compression						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Movement disorders (incl parkinsonism)						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Tremor						
Yes	1 (0.2)	1	0.2	1 (0.4)	2	0.7
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Essential tremor						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Mental impairment disorders						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	3 (0.7)	4	0.8
Memory impairment						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Dementia Alzheimer's type						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Disturbance in attention						
Yes	1 (0.2)	1	0.2	0		
No	0			3 (0.7)	4	0.8
Amnesia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cranial nerve disorders (excl neoplasms)						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	0		
Anosmia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Cranial nerve disorder						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Parosmia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Sleep disturbances (incl subtypes)						
Yes	2	(0.4)	2 0.3	0		
No	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Poor quality sleep						
Yes	2	(0.4)	2 0.3	0		
No	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Central nervous system vascular disorders						
Yes	1	(0.2)	1 0.2	0		
No	0			1	(0.2)	1 0.2
Cerebral infarction						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Ischaemic stroke						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Neuromuscular disorders						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Autonomic nervous system imbalance						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Increased intracranial pressure and hydrocephalus						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Idiopathic intracranial hypertension						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Neurological disorders of the eye						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Visual field defect						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Demyelinating disorders						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Multiple sclerosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Seizures (incl subtypes)						
Yes	0			0		
No	0			2 (0.5)	2	0.4
Partial seizures						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Psychogenic seizure						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue disorders						
Yes	134 (28.4)	225	35.6	83 (35.5)	138	45.3
No	204 (24.5)	333	31.0	103 (24.5)	166	31.6
Musculoskeletal and connective tissue disorders NEC						
Yes	72 (15.3)	90	14.2	40 (17.1)	53	17.4
No	115 (13.8)	154	14.3	59 (14.0)	79	15.0
Back pain						
Yes	35 (7.4)	43	6.8	23 (9.8)	24	7.9
No	72 (8.6)	78	7.3	31 (7.4)	32	6.1
Pain in extremity						
Yes	23 (4.9)	25	4.0	11 (4.7)	13	4.3
No	21 (2.5)	23	2.1	13 (3.1)	15	2.9
Musculoskeletal pain						
Yes	10 (2.1)	10	1.6	5 (2.1)	6	2.0
No	21 (2.5)	21	2.0	11 (2.6)	12	2.3
Neck pain						
Yes	6 (1.3)	6	0.9	1 (0.4)	1	0.3
No	13 (1.6)	15	1.4	8 (1.9)	8	1.5
Musculoskeletal chest pain						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	7 (0.8)	7	0.7	3 (0.7)	3	0.6
Musculoskeletal stiffness						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Flank pain						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Plantar fasciitis						
Yes	1 (0.2)	1	0.2	4 (1.7)	5	1.6
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Axillary mass						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Dupuytren's contracture						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Musculoskeletal discomfort						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Groin pain						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Limb mass						
Yes	0			0		
No	0			1 (0.2)	2	0.4
Muscle contracture						
Yes	0			1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Neck mass						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Joint disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	60 (12.7)	76	12.0	34 (14.5)	44	14.5
No	73 (8.8)	93	8.7	41 (9.7)	50	9.5
Arthralgia						
Yes	36 (7.6)	44	7.0	21 (9.0)	23	7.6
No	45 (5.4)	48	4.5	22 (5.2)	24	4.6
Osteoarthritis						
Yes	12 (2.5)	15	2.4	10 (4.3)	12	3.9
No	11 (1.3)	13	1.2	8 (1.9)	8	1.5
Spinal osteoarthritis						
Yes	6 (1.3)	6	0.9	0		
No	6 (0.7)	7	0.7	0		
Arthritis						
Yes	5 (1.1)	5	0.8	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Rotator cuff syndrome						
Yes	3 (0.6)	3	0.5	0		
No	3 (0.4)	3	0.3	5 (1.2)	5	1.0
Joint swelling						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Joint stiffness						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Vertebral foraminal stenosis						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	3	0.3	0		
Facet joint syndrome						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	2 (0.2)	3	0.3	0		
Arthropathy						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	2	0.2	0		
Periarthritis						
Yes	0			1 (0.4)	2	0.7
No	1 (0.1)	1	<0.1	0		
Spondylitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vertebral osteophyte						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Chondromalacia						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Haemarthrosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Joint noise						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Joint range of motion decreased						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Joint space narrowing						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Polyarthritis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Rheumatoid arthritis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Spondyloarthropathy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Muscle disorders						
Yes	24 (5.1)	26	4.1	11 (4.7)	12	3.9
No	34 (4.1)	38	3.5	12 (2.9)	17	3.2
Myalgia						
Yes	11 (2.3)	13	2.1	2 (0.9)	2	0.7
No	12 (1.4)	13	1.2	6 (1.4)	11	2.1
Muscle spasms						
Yes	7 (1.5)	7	1.1	7 (3.0)	8	2.6
No	12 (1.4)	12	1.1	3 (0.7)	3	0.6
Muscular weakness						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	5	0.5	1 (0.2)	1	0.2
Fibromyalgia						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Myofascial pain syndrome						

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Muscle fatigue						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Muscle tightness						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Myalgia intercostal						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Muscle disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Muscle twitching						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Myosclerosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Torticollis						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Tendon, ligament and cartilage disorders						
Yes	11 (2.3)	11	1.7	9 (3.8)	10	3.3
No	14 (1.7)	16	1.5	4 (1.0)	5	1.0

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tendonitis						
Yes	5 (1.1)	5	0.8	5 (2.1)	6	2.0
No	8 (1.0)	9	0.8	4 (1.0)	5	1.0
Costochondritis						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Tenosynovitis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Tendon disorder						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Osteochondrosis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Tendon discomfort						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Posterior tibial tendon dysfunction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Tendon pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Trigger finger						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)						
Yes	12 (2.5)	13	2.1	7 (3.0)	8	2.6
No	7 (0.8)	11	1.0	4 (1.0)	5	1.0
Intervertebral disc protrusion						
Yes	5 (1.1)	5	0.8	4 (1.7)	5	1.6
No	3 (0.4)	3	0.3	0		
Intervertebral disc degeneration						
Yes	3 (0.6)	3	0.5	0		
No	2 (0.2)	4	0.4	2 (0.5)	2	0.4
Scoliosis						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Cervical spinal stenosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Finger deformity						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Spinal stenosis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Intervertebral disc displacement						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Kyphoscoliosis						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Spondylolisthesis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Foot deformity						
Yes	0			2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Intervertebral disc annular tear						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Kyphosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Synovial and bursal disorders						
Yes	7 (1.5)	7	1.1	2 (0.9)	2	0.7
No	9 (1.1)	9	0.8	3 (0.7)	3	0.6
Bursitis						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	6 (0.7)	6	0.6	2 (0.5)	2	0.4
Synovial cyst						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Synovitis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bursal fluid accumulation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bone disorders (excl congenital and fractures)						
Yes	1 (0.2)	1	0.2	8 (3.4)	8	2.6
No	10 (1.2)	11	1.0	6 (1.4)	6	1.1
Osteopenia						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Pain in jaw						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Exostosis						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Bone cyst						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Coccydynia						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Metatarsalgia						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Osteonecrosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Osteoporosis						
Yes	0			3	(1.3)	3 1.0
No	1	(0.1)	1 <0.1	0		
Pubic pain						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Connective tissue disorders (excl congenital)						
Yes	1	(0.2)	1 0.2	1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Myofascitis						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Sjogren's syndrome						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Systemic lupus erythematosus						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Systemic scleroderma						
Yes	0			1	(0.4)	1 0.3
No	0			0		
General disorders and administration site conditions						
Yes	85	(18.0)	139 22.0	39	(16.7)	63 20.7
No	206	(24.7)	326 30.3	92	(21.9)	159 30.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
General system disorders NEC						
Yes	72 (15.3)	109	17.3	32 (13.7)	41	13.5
No	153 (18.3)	215	20.0	54 (12.8)	72	13.7
Fatigue						
Yes	29 (6.1)	35	5.5	9 (3.8)	9	3.0
No	75 (9.0)	85	7.9	19 (4.5)	20	3.8
Asthenia						
Yes	13 (2.8)	16	2.5	3 (1.3)	3	1.0
No	22 (2.6)	37	3.4	8 (1.9)	9	1.7
Early satiety						
Yes	10 (2.1)	10	1.6	0		
No	16 (1.9)	16	1.5	2 (0.5)	2	0.4
Pain						
Yes	5 (1.1)	6	0.9	2 (0.9)	2	0.7
No	16 (1.9)	17	1.6	5 (1.2)	5	1.0
Malaise						
Yes	7 (1.5)	10	1.6	0		
No	9 (1.1)	9	0.8	4 (1.0)	5	1.0
Influenza like illness						
Yes	5 (1.1)	5	0.8	3 (1.3)	3	1.0
No	12 (1.4)	13	1.2	10 (2.4)	10	1.9
Chest discomfort						
Yes	3 (0.6)	3	0.5	1 (0.4)	2	0.7
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Non-cardiac chest pain						
Yes	5 (1.1)	5	0.8	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Chills						
Yes	3 (0.6)	3	0.5	2 (0.9)	2	0.7
No	4 (0.5)	4	0.4	0		
Hunger						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	2 (0.5)	2	0.4
Oedema peripheral						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	6 (1.4)	6	1.1
Thirst						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Chest pain						
Yes	1 (0.2)	1	0.2	4 (1.7)	4	1.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Peripheral swelling						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	0			2 (0.5)	2	0.4
Swelling						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Feeling cold						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sensation of foreign body						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Feeling hot						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Hernia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Ill-defined disorder						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Swelling face						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Hangover						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Pseudocyst						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Sluggishness						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Axillary pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Crying						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Fat tissue increased						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Inflammation						
Yes	0			0		
No	1 (0.1)	2	0.2	1 (0.2)	1	0.2
Sense of oppression						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Discomfort						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Facial pain						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Granuloma						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Gravitational oedema						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Temperature intolerance						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Administration site reactions						
Yes	13 (2.8)	23	3.6	13 (5.6)	16	5.3
No	52 (6.2)	76	7.1	31 (7.4)	66	12.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Injection site bruising						
Yes	4 (0.8)	4	0.6	7 (3.0)	8	2.6
No	24 (2.9)	27	2.5	19 (4.5)	26	5.0
Injection site pain						
Yes	5 (1.1)	5	0.8	5 (2.1)	5	1.6
No	14 (1.7)	19	1.8	11 (2.6)	16	3.0
Injection site pruritus						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	8 (1.0)	8	0.7	0		
Injection site mass						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Injection site haematoma						
Yes	2 (0.4)	6	0.9	1 (0.4)	1	0.3
No	1 (0.1)	2	0.2	3 (0.7)	11	2.1
Injection site reaction						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Injection site erythema						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Injection site haemorrhage						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Injection site paraesthesia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Application site haematoma						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Injection site inflammation						
Yes	0			0		
No	2 (0.2)	4	0.4	0		
Infusion site extravasation						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Vessel puncture site rash						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Injection site induration						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Injection site swelling						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Injection site urticaria						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Vessel puncture site bruise						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Application site bruise						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Puncture site pain						
Yes	0			0		
No	0			1 (0.2)	2	0.4
Body temperature conditions						
Yes	3 (0.6)	4	0.6	5 (2.1)	5	1.6
No	24 (2.9)	29	2.7	12 (2.9)	16	3.0
Pyrexia						
Yes	3 (0.6)	4	0.6	5 (2.1)	5	1.6
No	24 (2.9)	29	2.7	12 (2.9)	16	3.0
Tissue disorders NEC						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Cyst						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Nodule						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Dysplasia						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Fat necrosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hyperplasia						
Yes	0			0		
No	0			1 (0.2)	1	0.2

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Complications associated with device						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Vascular stent occlusion						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Injury associated with device						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Therapeutic and nontherapeutic effects (excl toxicity)						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Withdrawal syndrome						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Metabolism and nutrition disorders						
Yes	69	(14.6)	92 14.6	32	(13.7)	44 14.5
No	130	(15.6)	175 16.3	51	(12.1)	64 12.2
Appetite and general nutritional disorders						
Yes	51	(10.8)	61 9.7	7	(3.0)	10 3.3
No	90	(10.8)	111 10.3	21	(5.0)	26 5.0
Decreased appetite						
Yes	45	(9.5)	51 8.1	6	(2.6)	7 2.3
No	79	(9.5)	88 8.2	16	(3.8)	19 3.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Food craving						
Yes	3 (0.6)	3	0.5	0		
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Hyperphagia						
Yes	3 (0.6)	4	0.6	1 (0.4)	3	1.0
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Increased appetite						
Yes	1 (0.2)	1	0.2	0		
No	5 (0.6)	6	0.6	2 (0.5)	2	0.4
Food aversion						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	5	0.5	0		
Lack of satiety						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Malnutrition						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vitamin related disorders						
Yes	7 (1.5)	8	1.3	3 (1.3)	4	1.3
No	15 (1.8)	20	1.9	7 (1.7)	8	1.5
Vitamin D deficiency						
Yes	6 (1.3)	6	0.9	3 (1.3)	3	1.0
No	11 (1.3)	11	1.0	5 (1.2)	5	1.0
Vitamin B12 deficiency						
Yes	1 (0.2)	1	0.2	0		
No	5 (0.6)	5	0.5	0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Folate deficiency						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Vitamin A deficiency						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vitamin B complex deficiency						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Vitamin B2 deficiency						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lipid metabolism disorders						
Yes	8 (1.7)	8	1.3	9 (3.8)	10	3.3
No	12 (1.4)	13	1.2	11 (2.6)	11	2.1
Dyslipidaemia						
Yes	5 (1.1)	5	0.8	6 (2.6)	7	2.3
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Hypercholesterolaemia						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Hypertriglyceridaemia						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Hyperlipidaemia						
Yes	1 (0.2)	1	0.2	0		
No	0			4 (1.0)	4	0.8

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cholesterosis						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Electrolyte and fluid balance conditions						
Yes	5 (1.1)	7	1.1	4 (1.7)	4	1.3
No	4 (0.5)	5	0.5	2 (0.5)	2	0.4
Hypokalaemia						
Yes	3 (0.6)	5	0.8	2 (0.9)	2	0.7
No	0			0		
Hyperkalaemia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Hyponatraemia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Dehydration						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Electrolyte imbalance						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Polydipsia						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Fluid retention						
Yes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Glucose metabolism disorders (incl diabetes mellitus)						
Yes	2 (0.4)	2	0.3	10 (4.3)	13	4.3
No	8 (1.0)	15	1.4	11 (2.6)	12	2.3
Hypoglycaemia						
Yes	2 (0.4)	2	0.3	2 (0.9)	3	1.0
No	5 (0.6)	11	1.0	3 (0.7)	4	0.8
Glucose tolerance impaired						
Yes	0			3 (1.3)	3	1.0
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Postprandial hypoglycaemia						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Type 2 diabetes mellitus						
Yes	0			3 (1.3)	4	1.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Diabetes mellitus						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Hyperglycaemia						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Impaired fasting glucose						
Yes	0			1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Insulin resistance						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Iron and trace metal metabolism disorders						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	4	0.4	4 (1.0)	4	0.8
Iron deficiency						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	4	0.4	4 (1.0)	4	0.8
Purine and pyrimidine metabolism disorders						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	2 (0.2)	3	0.3	1 (0.2)	1	0.2
Gout						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	2 (0.2)	3	0.3	1 (0.2)	1	0.2
Hyperuricaemia						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Food intolerance syndromes						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Lactose intolerance						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Dairy intolerance						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Food intolerance						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Metabolism disorders NEC						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Hyperlipasaemia						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Bone, calcium, magnesium and phosphorus metabolism disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hypomagnesaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Protein and amino acid metabolism disorders NEC						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hypoalbuminaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Injury, poisoning and procedural complications						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	69 (14.6)	99	15.7	43 (18.4)	68	22.3
No	119 (14.3)	165	15.4	78 (18.5)	108	20.6
Injuries NEC						
Yes	41 (8.7)	51	8.1	34 (14.5)	48	15.8
No	85 (10.2)	117	10.9	62 (14.7)	82	15.6
Ligament sprain						
Yes	8 (1.7)	9	1.4	7 (3.0)	8	2.6
No	13 (1.6)	15	1.4	12 (2.9)	12	2.3
Fall						
Yes	7 (1.5)	7	1.1	3 (1.3)	3	1.0
No	12 (1.4)	12	1.1	9 (2.1)	16	3.0
Muscle strain						
Yes	5 (1.1)	5	0.8	7 (3.0)	7	2.3
No	12 (1.4)	13	1.2	8 (1.9)	8	1.5
Contusion						
Yes	3 (0.6)	5	0.8	6 (2.6)	7	2.3
No	12 (1.4)	14	1.3	9 (2.1)	12	2.3
Skin laceration						
Yes	3 (0.6)	3	0.5	5 (2.1)	6	2.0
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Arthropod bite						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	7 (0.8)	7	0.7	6 (1.4)	6	1.1
Arthropod sting						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Limb injury						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	3 (0.7)	3	0.6
Skin abrasion						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	3 (0.4)	6	0.6	0		
Tooth fracture						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	3 (0.4)	3	0.3	0		
Epicondylitis						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	4 (1.0)	4	0.8
Concussion						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Ligament rupture						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Muscle rupture						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Road traffic accident						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Animal bite						
Yes	0			0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Back injury						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Wound						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Injury						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Eye burns						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Foreign body in eye						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Musculoskeletal injury						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Post-traumatic pain						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Skeletal injury						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Soft tissue foreign body						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Subdural haematoma						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bone contusion						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Eyelid contusion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eyelid injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Face injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Head injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Ligament injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Muscle injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nerve injury						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Post-traumatic neck syndrome						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Tendon injury						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Chest injury						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Corneal abrasion						
Yes	0			1	(0.4)	1 0.3
No	0			1	(0.2)	1 0.2
Eye injury						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Gun shot wound						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Post concussion syndrome						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Scar						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Tendon rupture						
Yes	0			1	(0.4)	2 0.7
No	0			1	(0.2)	1 0.2
Bone and joint injuries						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	17 (3.6)	20	3.2	11 (4.7)	12	3.9
No	18 (2.2)	19	1.8	11 (2.6)	11	2.1
Foot fracture						
Yes	2 (0.4)	3	0.5	2 (0.9)	2	0.7
No	3 (0.4)	4	0.4	3 (0.7)	3	0.6
Meniscus injury						
Yes	3 (0.6)	3	0.5	4 (1.7)	5	1.6
No	1 (0.1)	1	<0.1	0		
Joint injury						
Yes	1 (0.2)	1	0.2	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Rib fracture						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	0			0		
Radius fracture						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hand fracture						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Joint dislocation						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Femur fracture						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Fractured coccyx						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Spinal compression fracture								
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Thoracic vertebral fracture								
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Wrist fracture								
Yes	1	(0.2)	1	0.2	0			
No	0				1	(0.2)	1	0.2
Ankle fracture								
Yes	0				0			
No	1	(0.1)	1	<0.1	2	(0.5)	2	0.4
Facial bones fracture								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Stress fracture								
Yes	0				0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Tibia fracture								
Yes	0				1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Upper limb fracture								
Yes	0				1	(0.4)	1	0.3
No	1	(0.1)	1	<0.1	0			
Fibula fracture								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Torus fracture						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Procedural related injuries and complications NEC						
Yes	12 (2.5)	19	3.0	6 (2.6)	6	2.0
No	15 (1.8)	16	1.5	5 (1.2)	7	1.3
Procedural pain						
Yes	7 (1.5)	8	1.3	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	5 (1.2)	7	1.3
Injection related reaction						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	0		
Post procedural complication						
Yes	1 (0.2)	2	0.3	0		
No	3 (0.4)	3	0.3	0		
Administration related reaction						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Procedural nausea						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Anaemia postoperative						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Anaphylactic transfusion reaction						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Post procedural constipation						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Post procedural haemorrhage						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Urinary retention postoperative						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Procedural haemorrhage						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Suture related complication						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaccination complication						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Procedural vomiting						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Seroma						
Yes	0			1 (0.4)	1	0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Medication errors and other product use errors and issues						
Yes	4 (0.8)	4	0.6	0		
No	6 (0.7)	6	0.6	2 (0.5)	3	0.6
Accidental overdose						
Yes	2 (0.4)	2	0.3	0		
No	5 (0.6)	5	0.5	2 (0.5)	3	0.6
Incorrect dose administered						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Medication error						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Injuries by physical agents						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Sunburn						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Heat exhaustion						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Thermal burn						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Heat illness						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	1	(0.1)	1	<0.1	0			
Hypobarism								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Burns second degree								
Yes	0				1	(0.4)	1	0.3
No	0				2	(0.5)	2	0.4
Overdoses and underdoses NEC								
Yes	3	(0.6)	3	0.5	0			
No	1	(0.1)	1	<0.1	2	(0.5)	2	0.4
Overdose								
Yes	3	(0.6)	3	0.5	0			
No	1	(0.1)	1	<0.1	2	(0.5)	2	0.4
Exposures, chemical injuries and poisoning								
Yes	0				0			
No	2	(0.2)	2	0.2	0			
Exposure to toxic agent								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Reactive gastropathy								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Skin and subcutaneous tissue disorders								
Yes	60	(12.7)	84	13.3	28	(12.0)	33	10.8
No	128	(15.3)	165	15.4	47	(11.2)	63	12.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Epidermal and dermal conditions						
Yes	34 (7.2)	46	7.3	21 (9.0)	23	7.6
No	71 (8.5)	83	7.7	31 (7.4)	42	8.0
Rash						
Yes	7 (1.5)	10	1.6	6 (2.6)	6	2.0
No	19 (2.3)	20	1.9	11 (2.6)	17	3.2
Pruritus						
Yes	7 (1.5)	7	1.1	1 (0.4)	1	0.3
No	10 (1.2)	11	1.0	5 (1.2)	5	1.0
Eczema						
Yes	4 (0.8)	4	0.6	1 (0.4)	1	0.3
No	9 (1.1)	9	0.8	3 (0.7)	3	0.6
Dry skin						
Yes	3 (0.6)	3	0.5	3 (1.3)	3	1.0
No	5 (0.6)	5	0.5	0		
Skin burning sensation						
Yes	2 (0.4)	8	1.3	2 (0.9)	2	0.7
No	4 (0.5)	4	0.4	0		
Dermatitis contact						
Yes	2 (0.4)	3	0.5	3 (1.3)	3	1.0
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Skin lesion						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Erythema						
Yes	3 (0.6)	3	0.5	2 (0.9)	2	0.7
No	0			2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Psoriasis						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Rash pruritic						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Skin irritation						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Dermatitis						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pain of skin						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Decubitus ulcer						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Dermatitis allergic						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Blister						
Yes	0			2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Skin disorder						
Yes	0			0		
No	2 (0.2)	3	0.3	1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Dermatitis atopic						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Macule						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Papule						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Perioral dermatitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pityriasis rosea						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Prurigo						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Rash maculo-papular						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin discolouration						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Skin odour abnormal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Xanthelasma						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Drug eruption						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Photosensitivity reaction						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Rash erythematous						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Rash macular						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skin reaction						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skin appendage conditions						
Yes	25 (5.3)	28	4.4	6 (2.6)	7	2.3
No	57 (6.8)	64	6.0	13 (3.1)	14	2.7
Alopecia						
Yes	13 (2.8)	14	2.2	1 (0.4)	1	0.3
No	40 (4.8)	41	3.8	4 (1.0)	4	0.8
Hyperhidrosis						
Yes	3 (0.6)	3	0.5	3 (1.3)	3	1.0
No	5 (0.6)	5	0.5	5 (1.2)	5	1.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Acne						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Ingrowing nail						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	1 (0.1)	1	<0.1	0		
Cold sweat						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Miliaria						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Hirsutism						
Yes	0			0		
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Hair growth abnormal						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Rosacea						
Yes	1 (0.2)	2	0.3	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Hidradenitis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Hypertrichosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Diffuse alopecia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nail bed inflammation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nail discolouration						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Night sweats						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Onychoclasis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Angioedema and urticaria						
Yes	6 (1.3)	6	0.9	2 (0.9)	2	0.7
No	7 (0.8)	7	0.7	4 (1.0)	4	0.8
Urticaria						
Yes	6 (1.3)	6	0.9	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Cold urticaria						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Angioedema						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cornification and dystrophic skin disorders						
Yes	3 (0.6)	4	0.6	0		
No	4 (0.5)	5	0.5	0		
Actinic keratosis						
Yes	3 (0.6)	4	0.6	0		
No	0			0		
Hyperkeratosis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Lichenoid keratosis						
Yes	0			0		
No	1 (0.1)	2	0.2	0		
Skin striae						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pigmentation disorders						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Ephelides						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Skin hyperpigmentation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cutaneous neoplasms benign						
Yes	0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	2	(0.2)	2	0.2	0			
Dermal cyst								
Yes	0				1	(0.4)	1	0.3
No	2	(0.2)	2	0.2	0			
Skin vascular abnormalities								
Yes	0				0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Ecchymosis								
Yes	0				0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Skin and subcutaneous tissue disorders NEC								
Yes	0				0			
No	0				2	(0.5)	2	0.4
Erythema nodosum								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Skin ulcer								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Respiratory, thoracic and mediastinal disorders								
Yes	59	(12.5)	76	12.0	36	(15.4)	46	15.1
No	114	(13.7)	149	13.9	68	(16.2)	88	16.8
Respiratory tract signs and symptoms								
Yes	25	(5.3)	27	4.3	10	(4.3)	10	3.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	50 (6.0)	54	5.0	23 (5.5)	27	5.1
Oropharyngeal pain						
Yes	13 (2.8)	14	2.2	5 (2.1)	5	1.6
No	35 (4.2)	39	3.6	18 (4.3)	21	4.0
Rhinorrhoea						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Upper respiratory tract inflammation						
Yes	3 (0.6)	4	0.6	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Hiccups						
Yes	3 (0.6)	3	0.5	0		
No	0			0		
Upper-airway cough syndrome						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Dysphonia						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Catarrh						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Paranasal sinus discomfort						
Yes	1 (0.2)	1	0.2	0		
No	0			2 (0.5)	2	0.4
Diaphragmalgia						
Yes	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Oropharyngeal discomfort						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pleuritic pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sinus pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Yawning						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Upper respiratory tract congestion						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Respiratory disorders NEC						
Yes	18 (3.8)	20	3.2	18 (7.7)	20	6.6
No	43 (5.2)	50	4.7	33 (7.8)	36	6.9
Cough						
Yes	9 (1.9)	10	1.6	10 (4.3)	11	3.6
No	31 (3.7)	35	3.3	23 (5.5)	24	4.6
Dyspnoea						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	6 (0.7)	6	0.6	5 (1.2)	5	1.0
Sleep apnoea syndrome						
Yes	3 (0.6)	3	0.5	3 (1.3)	3	1.0

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Productive cough						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Haemoptysis						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Dyspnoea exertional						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Respiratory disorder						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Respiratory tract congestion						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Hyperventilation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Acute respiratory failure						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Pulmonary mass						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Upper respiratory tract disorders (excl infections)						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	18 (3.8)	18	2.8	5 (2.1)	7	2.3
No	33 (4.0)	35	3.3	13 (3.1)	14	2.7
Sinus congestion						
Yes	3 (0.6)	3	0.5	1 (0.4)	3	1.0
No	10 (1.2)	10	0.9	4 (1.0)	4	0.8
Rhinitis allergic						
Yes	3 (0.6)	3	0.5	2 (0.9)	2	0.7
No	8 (1.0)	8	0.7	4 (1.0)	5	1.0
Nasal congestion						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	9 (1.1)	9	0.8	4 (1.0)	4	0.8
Epistaxis						
Yes	4 (0.8)	4	0.6	0		
No	3 (0.4)	3	0.3	0		
Nasal polyps						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Nasal septum deviation						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Paranasal sinus hypersecretion						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Tonsillar hypertrophy						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Nasal dryness						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Paranasal cyst						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Vocal cord polyp						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nasal adhesions						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Bronchial disorders (excl neoplasms)						
Yes	8 (1.7)	8	1.3	6 (2.6)	7	2.3
No	6 (0.7)	6	0.6	7 (1.7)	9	1.7
Asthma						
Yes	5 (1.1)	5	0.8	4 (1.7)	4	1.3
No	6 (0.7)	6	0.6	5 (1.2)	7	1.3
Chronic obstructive pulmonary disease						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Wheezing						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Allergic bronchitis						
Yes	0			1 (0.4)	2	0.7
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Lower respiratory tract disorders (excl obstruction and infection)						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Atelectasis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Pulmonary fibrosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pleural disorders						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Pleural effusion						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Pleurisy						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Pulmonary vascular disorders						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Pulmonary embolism						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Psychiatric disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	38 (8.1)	48	7.6	36 (15.4)	44	14.5
No	86 (10.3)	112	10.4	47 (11.2)	69	13.1
Anxiety disorders and symptoms						
Yes	14 (3.0)	14	2.2	14 (6.0)	14	4.6
No	32 (3.8)	34	3.2	17 (4.0)	18	3.4
Anxiety						
Yes	11 (2.3)	11	1.7	11 (4.7)	11	3.6
No	21 (2.5)	22	2.0	9 (2.1)	9	1.7
Stress						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	4 (1.0)	4	0.8
Panic attack						
Yes	0			0		
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Post-traumatic stress disorder						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Acute stress disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Burnout syndrome						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Nervousness						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Agitation						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Generalised anxiety disorder						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Sleep disorders and disturbances						
Yes	12 (2.5)	13	2.1	15 (6.4)	16	5.3
No	28 (3.4)	29	2.7	14 (3.3)	17	3.2
Insomnia						
Yes	7 (1.5)	7	1.1	9 (3.8)	9	3.0
No	21 (2.5)	22	2.0	9 (2.1)	10	1.9
Sleep disorder						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	5 (1.2)	6	1.1
Initial insomnia						
Yes	3 (0.6)	4	0.6	1 (0.4)	1	0.3
No	0			0		
Nightmare						
Yes	1 (0.2)	1	0.2	2 (0.9)	3	1.0
No	0			0		
Abnormal dreams						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Middle insomnia						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Sleep terror						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Depressed mood disorders and disturbances						
Yes	7 (1.5)	8	1.3	11 (4.7)	11	3.6
No	26 (3.1)	31	2.9	16 (3.8)	18	3.4
Depressed mood						
Yes	4 (0.8)	4	0.6	3 (1.3)	3	1.0
No	10 (1.2)	11	1.0	6 (1.4)	6	1.1
Depression						
Yes	1 (0.2)	2	0.3	6 (2.6)	6	2.0
No	14 (1.7)	15	1.4	8 (1.9)	9	1.7
Major depression						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Anhedonia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Negative thoughts						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Tearfulness						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Depressive symptom						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Persistent depressive disorder						
Yes	0			2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Mood disorders and disturbances NEC						
Yes	3 (0.6)	3	0.5	0		
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Irritability						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Apathy						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Affective disorder						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Mood swings						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Sexual dysfunctions, disturbances and gender identity disorders						
Yes	3 (0.6)	3	0.5	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Libido decreased						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Libido increased						
Yes	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Changes in physical activity						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	0		
Restlessness						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Tic						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Suicidal and self-injurious behaviours NEC						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	3 (0.7)	5	1.0
Suicidal ideation						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	2 (0.5)	4	0.8
Suicide attempt						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Adjustment disorders (incl subtypes)						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Adjustment disorder						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Adjustment disorder with depressed mood						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Grief reaction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cognitive and attention disorders and disturbances						
Yes	1 (0.2)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Mental fatigue						
Yes	1 (0.2)	2	0.3	0		
No	0			0		
Attention deficit/hyperactivity disorder						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Psychiatric and behavioural symptoms NEC						
Yes	1 (0.2)	1	0.2	0		
No	0			2 (0.5)	2	0.4
Abulia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Psychiatric symptom						
Yes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			2	(0.5)	2 0.4
Deliria (incl confusion)						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	2 0.2	0		
Disorientation						
Yes	0			1	(0.4)	1 0.3
No	1	(0.1)	2 0.2	0		
Manic and bipolar mood disorders and disturbances						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Bipolar disorder						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Psychiatric disorders NEC						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Alcoholic hangover						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Somatic symptom and related disorders						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Conversion disorder						
Yes	0			0		
No	0			1	(0.2)	1 0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Vascular disorders						
Yes	47 (10.0)	52	8.2	23 (9.8)	27	8.9
No	43 (5.2)	45	4.2	22 (5.2)	23	4.4
Vascular hypertensive disorders						
Yes	26 (5.5)	26	4.1	13 (5.6)	17	5.6
No	16 (1.9)	16	1.5	15 (3.6)	15	2.9
Hypertension						
Yes	24 (5.1)	24	3.8	12 (5.1)	16	5.3
No	16 (1.9)	16	1.5	15 (3.6)	15	2.9
Essential hypertension						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Hypertensive emergency						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Hypertensive crisis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Decreased and nonspecific blood pressure disorders and shock						
Yes	9 (1.9)	11	1.7	1 (0.4)	1	0.3
No	10 (1.2)	10	0.9	1 (0.2)	1	0.2
Hypotension						
Yes	6 (1.3)	7	1.1	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Orthostatic hypotension						
Yes	2 (0.4)	3	0.5	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	6 (0.7)	6	0.6	0		
Circulatory collapse						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Vascular disorders NEC						
Yes	6 (1.3)	7	1.1	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Hot flush						
Yes	6 (1.3)	6	0.9	2 (0.9)	2	0.7
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Flushing						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Arteriosclerosis, stenosis, vascular insufficiency and necrosis						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Peripheral venous disease						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Peripheral coldness						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Aortic arteriosclerosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Arteriosclerosis						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Raynaud's phenomenon						
Yes	0			1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Vascular haemorrhagic disorders						
Yes	2 (0.4)	2	0.3	4 (1.7)	4	1.3
No	4 (0.5)	4	0.4	0		
Haematoma						
Yes	2 (0.4)	2	0.3	4 (1.7)	4	1.3
No	4 (0.5)	4	0.4	0		
Venous varices						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	0		
Varicose vein						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	0		
Embolism and thrombosis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Thrombosis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Thrombophlebitis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Deep vein thrombosis						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.4)	1 0.3
No	0			0		
Thrombophlebitis superficial						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Vascular infections and inflammations						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Arteritis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Phlebitis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Lymphatic vessel disorders						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Lymphoedema						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Reproductive system and breast disorders						
Yes	28	(5.9)	36 5.7	6	(2.6)	7 2.3
No	68	(8.2)	86 8.0	26	(6.2)	32 6.1
Menstrual cycle and uterine bleeding disorders						
Yes	10	(2.1)	12 1.9	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	35 (4.2)	41	3.8	7 (1.7)	10	1.9
Menstruation irregular						
Yes	2 (0.4)	2	0.3	0		
No	12 (1.4)	12	1.1	0		
Menorrhagia						
Yes	2 (0.4)	2	0.3	0		
No	8 (1.0)	10	0.9	3 (0.7)	3	0.6
Dysmenorrhoea						
Yes	4 (0.8)	4	0.6	0		
No	3 (0.4)	4	0.4	1 (0.2)	3	0.6
Metrorrhagia						
Yes	1 (0.2)	1	0.2	0		
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Menstrual disorder						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	0		
Dysfunctional uterine bleeding						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	0		
Amenorrhoea						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Menstruation delayed						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Oligomenorrhoea						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Premenstrual syndrome						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Premenstrual pain						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Breast disorders						
Yes	5 (1.1)	6	0.9	2 (0.9)	2	0.7
No	12 (1.4)	14	1.3	5 (1.2)	6	1.1
Breast mass						
Yes	2 (0.4)	2	0.3	0		
No	6 (0.7)	6	0.6	1 (0.2)	2	0.4
Breast cyst						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Breast disorder						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Breast pain						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Fibrocystic breast disease						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Nipple pain						
Yes	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			0		
Breast inflammation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Breast fibrosis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Breast haematoma						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Uterine, pelvic and broad ligament disorders						
Yes	4 (0.8)	4	0.6	0		
No	7 (0.8)	7	0.7	2 (0.5)	2	0.4
Uterine haemorrhage						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Endometriosis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Uterine polyp						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Adenomyosis						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Uterine enlargement						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaginal prolapse						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Menopause related conditions						
Yes	6 (1.3)	6	0.9	0		
No	3 (0.4)	3	0.3	4 (1.0)	5	1.0
Atrophic vulvovaginitis						
Yes	3 (0.6)	3	0.5	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Menopausal symptoms						
Yes	3 (0.6)	3	0.5	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Postmenopausal haemorrhage						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	2	0.4
Ovarian and fallopian tube disorders						
Yes	2 (0.4)	2	0.3	0		
No	7 (0.8)	7	0.7	3 (0.7)	3	0.6
Ovarian cyst						
Yes	2 (0.4)	2	0.3	0		
No	5 (0.6)	5	0.5	2 (0.5)	2	0.4
Hydrosalpinx						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Polycystic ovaries						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Vulvovaginal disorders (excl infections and inflammations)						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	8 (1.0)	8	0.7	3 (0.7)	3	0.6
Vaginal haemorrhage						
Yes	0			0		
No	6 (0.7)	6	0.6	2 (0.5)	2	0.4
Vulvovaginal dryness						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Vulvovaginal discomfort						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vulvovaginal pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Vaginal polyp						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Vulvovaginal pruritus						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Reproductive tract disorders NEC						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pelvic pain						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Genital rash						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Genital pain						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Cervix disorders (excl infections and inflammations)						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Cervical dysplasia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Cervical leukoplakia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Uterine cervical erosion						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Sexual function and fertility disorders						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Dyspareunia						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Erectile dysfunction						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Testicular and epididymal disorders						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Testicular mass						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Testicular pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Testicular disorder						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Prostatic disorders (excl infections and inflammations)						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Benign prostatic hyperplasia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Female reproductive tract infections and inflammations						
Yes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Uterine inflammation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Penile and scrotal disorders (excl infections and inflammations)						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Scrotal pain						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Investigations						
Yes	30 (6.4)	37	5.9	24 (10.3)	31	10.2
No	63 (7.6)	81	7.5	25 (5.9)	36	6.9
Hepatobiliary investigations						
Yes	5 (1.1)	5	0.8	4 (1.7)	5	1.6
No	11 (1.3)	12	1.1	7 (1.7)	10	1.9
Gamma-glutamyltransferase increased						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	2 (0.5)	2	0.4
Hepatic enzyme increased						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	5 (0.6)	5	0.5	1 (0.2)	1	0.2
Aspartate aminotransferase increased						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			3 (0.7)	3	0.6

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Alanine aminotransferase increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Blood bilirubin increased						
Yes	0			2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	0		
Transaminases increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Protein and chemistry analyses NEC						
Yes	7 (1.5)	7	1.1	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
C-reactive protein increased						
Yes	7 (1.5)	7	1.1	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	3 (0.7)	3	0.6
Gastrointestinal investigations						
Yes	5 (1.1)	6	0.9	2 (0.9)	2	0.7
No	8 (1.0)	9	0.8	0		
Lipase increased						
Yes	5 (1.1)	5	0.8	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	0		
Amylase increased						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Gastric pH						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Pancreatic enzymes increased						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Cardiac and vascular investigations (excl enzyme tests)						
Yes	7	(1.5)	8 1.3	3	(1.3)	3 1.0
No	3	(0.4)	4 0.4	4	(1.0)	4 0.8
QRS axis abnormal						
Yes	2	(0.4)	2 0.3	0		
No	0			0		
Heart rate increased						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Blood pressure abnormal						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Blood pressure decreased						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Blood pressure increased						
Yes	1	(0.2)	1 0.2	2	(0.9)	2 0.7
No	0			4	(1.0)	4 0.8
Electrocardiogram ST segment depression						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Pulse abnormal						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Cardiac murmur						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave amplitude decreased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave inversion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave abnormal						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Endocrine investigations (incl sex hormones)						
Yes	2 (0.4)	4	0.6	3 (1.3)	3	1.0
No	6 (0.7)	6	0.6	0		
Blood calcitonin increased						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Blood thyroid stimulating hormone decreased						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		
Thyroxine free increased						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Thyroxine increased								
Yes	1	(0.2)	1	0.2	0			
No	0				0			
Blood thyroid stimulating hormone abnormal								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Blood thyroid stimulating hormone increased								
Yes	0				1	(0.4)	1	0.3
No	0				0			
Lipid analyses								
Yes	0				1	(0.4)	1	0.3
No	9	(1.1)	16	1.5	3	(0.7)	4	0.8
High density lipoprotein decreased								
Yes	0				0			
No	5	(0.6)	5	0.5	0			
Blood cholesterol increased								
Yes	0				0			
No	4	(0.5)	4	0.4	1	(0.2)	1	0.2
Low density lipoprotein increased								
Yes	0				0			
No	3	(0.4)	3	0.3	2	(0.5)	2	0.4
Lipids increased								
Yes	0				1	(0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	0		
Blood triglycerides increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Very low density lipoprotein increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Enzyme investigations NEC						
Yes	2 (0.4)	2	0.3	5 (2.1)	5	1.6
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Blood creatine phosphokinase increased						
Yes	2 (0.4)	2	0.3	4 (1.7)	4	1.3
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Enzyme level increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blood alkaline phosphatase increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Physical examination and organ system status topics						
Yes	0			1 (0.4)	2	0.7
No	7 (0.8)	7	0.7	2 (0.5)	2	0.4
Weight decreased						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	3 (0.4)	3	0.3	0		
Weight increased						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Body mass index decreased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Respiratory rate increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Body temperature increased						
Yes	0			1 (0.4)	2	0.7
No	0			0		
Microbiology and serology investigations						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	0		
HIV test positive						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Helicobacter test positive						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Human papilloma virus test positive						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Haematology investigations (incl blood groups)						
Yes	2 (0.4)	2	0.3	2 (0.9)	5	1.6
No	1 (0.1)	1	<0.1	0		
Haemoglobin decreased						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Haematology test abnormal						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Haematocrit increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Haemoglobin increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Red blood cell count increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Red cell distribution width increased						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Renal and urinary tract investigations and urinalyses						
Yes	0			1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	2 (0.5)	2	0.4

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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood creatinine increased						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Glomerular filtration rate decreased						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
White blood cells urine						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blood urine present						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Investigations, imaging and histopathology procedures NEC						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Precancerous cells present						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Smear test						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Endoscopy						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Cytogenetic investigations						
Yes	0			0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Prostatic specific antigen increased						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Metabolic, nutritional and blood gas investigations						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Blood glucose increased						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Blood uric acid increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Glycosylated haemoglobin increased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Vitamin D decreased						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Reproductive organ and breast investigations (excl hormone analyses)						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Biopsy breast						
Yes	0			0		
No	2 (0.2)	2	0.2	0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Water, electrolyte and mineral investigations						
Yes	0			0		
No	2	(0.2)	2 0.2	3	(0.7)	3 0.6
Blood calcium decreased						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Blood potassium increased						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Blood iron decreased						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Blood sodium increased						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Serum ferritin decreased						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Musculoskeletal and soft tissue investigations (excl enzyme tests)						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Arthroscopy						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Immunology and allergy investigations						

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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Antinuclear antibody positive						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Cardiac disorders						
Yes	25 (5.3)	31	4.9	12 (5.1)	15	4.9
No	29 (3.5)	31	2.9	21 (5.0)	29	5.5
Cardiac arrhythmias						
Yes	16 (3.4)	21	3.3	4 (1.7)	5	1.6
No	16 (1.9)	17	1.6	13 (3.1)	16	3.0
Atrial fibrillation						
Yes	6 (1.3)	9	1.4	1 (0.4)	2	0.7
No	0			2 (0.5)	2	0.4
Atrioventricular block first degree						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	3 (0.7)	3	0.6
Tachycardia						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	5 (1.2)	5	1.0
Bundle branch block left						
Yes	2 (0.4)	2	0.3	0		
No	0			0		
Ventricular extrasystoles						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Arrhythmia						
Yes	0			0		
No	2 (0.2)	2	0.2	2 (0.5)	2	0.4
Sinus tachycardia						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Atrial flutter						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Atrioventricular block second degree						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bradycardia						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			2 (0.5)	2	0.4
Defect conduction intraventricular						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Nodal rhythm						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Atrial tachycardia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Atrioventricular block						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Bundle branch block right						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Cardiac flutter						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Sinus bradycardia						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Supraventricular extrasystoles						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cardiac disorders, signs and symptoms NEC						
Yes	3 (0.6)	3	0.5	3 (1.3)	3	1.0
No	9 (1.1)	9	0.8	5 (1.2)	7	1.3
Palpitations						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	8 (1.0)	8	0.7	5 (1.2)	7	1.3
Cardiovascular disorder						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Hypertensive heart disease						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Coronary artery disorders						
Yes	5 (1.1)	5	0.8	3 (1.3)	3	1.0

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	2 (0.2)	2	0.2	4 (1.0)	5	1.0
Angina pectoris						
Yes	2 (0.4)	2	0.3	2 (0.9)	2	0.7
No	0			2 (0.5)	2	0.4
Acute myocardial infarction						
Yes	0			0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Angina unstable						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Arteriosclerosis coronary artery						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Coronary artery stenosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Coronary artery disease						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Myocardial infarction						
Yes	0			1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Cardiac valve disorders						
Yes	0			1 (0.4)	2	0.7
No	2 (0.2)	2	0.2	0		
Aortic valve incompetence						
Yes	0			0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Aortic valve sclerosis						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Mitral valve incompetence						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Tricuspid valve incompetence						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Cardiac neoplasms						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Pericardial cyst						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Myocardial disorders						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	0			1 (0.2)	1	0.2
Left ventricular hypertrophy						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Cardiomegaly						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Cardiomyopathy						
Yes	0			0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Myocarditis						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Pericardial disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pericardial disease						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Yes	19 (4.0)	25	4.0	11 (4.7)	13	4.3
No	27 (3.2)	27	2.5	14 (3.3)	14	2.7
Cutaneous neoplasms benign						
Yes	3 (0.6)	7	1.1	4 (1.7)	4	1.3
No	7 (0.8)	7	0.7	2 (0.5)	2	0.4
Melanocytic naevus						
Yes	3 (0.6)	4	0.6	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Acrochordon						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Seborrhoeic keratosis						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Dysplastic naevus						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin papilloma						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Pyogenic granuloma						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Reproductive neoplasms female benign						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	4 (1.0)	4	0.8
Uterine leiomyoma						
Yes	2 (0.4)	2	0.3	0		
No	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Ovarian adenoma						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Soft tissue neoplasms benign						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Lipoma						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Leiomyoma						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast neoplasms malignant and unspecified (incl nipple)						
Yes	3 (0.6)	3	0.5	2 (0.9)	2	0.7
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Intraductal proliferative breast lesion						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	0			0		
Breast cancer						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Invasive ductal breast carcinoma						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lobular breast carcinoma in situ						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Phyllodes tumour						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skin neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.2	2 (0.9)	2	0.7
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Basal cell carcinoma						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Malignant melanoma						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Malignant melanoma in situ						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Neoplasm skin						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Gastrointestinal neoplasms benign						
Yes	2	(0.4)	2 0.3	0		
No	1	(0.1)	1 <0.1	0		
Colon adenoma						
Yes	2	(0.4)	2 0.3	0		
No	1	(0.1)	1 <0.1	0		
Miscellaneous and site unspecified neoplasms malignant and unspecified						
Yes	2	(0.4)	2 0.3	0		
No	0			0		
Neoplasm						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Squamous cell carcinoma						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Breast neoplasms benign (incl nipple)						
Yes	1	(0.2)	1 0.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Benign breast neoplasm						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Endocrine neoplasms benign						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Benign neoplasm of thyroid gland						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Parathyroid tumour benign						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hepatic and biliary neoplasms benign						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Haemangioma of liver						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Hepatobiliary neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Hepatic neoplasm						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Miscellaneous and site unspecified neoplasms benign						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Fibroma						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Adenoma benign						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Skeletal neoplasms benign						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Haemangioma of bone						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Soft tissue neoplasms malignant and unspecified						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Dermatofibrosarcoma protuberans						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Endocrine neoplasms malignant and unspecified						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Papillary thyroid cancer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal neoplasms malignant and unspecified						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Gastrointestinal stromal tumour						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Reproductive neoplasms female malignant and unspecified						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Cervix carcinoma stage 0						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Reproductive neoplasms male malignant and unspecified						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Prostate cancer						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Leukaemias						
Yes	0			1 (0.4)	1	0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hairy cell leukaemia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Nervous system neoplasms malignant and unspecified NEC						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Glioblastoma						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Ocular neoplasms						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Eyelid haemangioma						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Plasma cell neoplasms						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Paraproteinaemia						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Renal and urinary tract neoplasms benign						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Kidney angiomyolipoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3
No	0			0		
Renal and urinary tract neoplasms malignant and unspecified						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Urinary tract neoplasm						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Eye disorders						
Yes	20 (4.2)	27	4.3	14 (6.0)	18	5.9
No	24 (2.9)	31	2.9	10 (2.4)	13	2.5
Vision disorders						
Yes	6 (1.3)	7	1.1	1 (0.4)	1	0.3
No	8 (1.0)	10	0.9	3 (0.7)	3	0.6
Vision blurred						
Yes	2 (0.4)	2	0.3	0		
No	4 (0.5)	4	0.4	1 (0.2)	1	0.2
Diplopia						
Yes	2 (0.4)	3	0.5	0		
No	1 (0.1)	1	<0.1	0		
Myopia						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Visual impairment						
Yes	1 (0.2)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			1	(0.2)	1 0.2
Anisometropia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Astigmatism						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Photopsia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Scintillating scotoma						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Ocular infections, irritations and inflammations						
Yes	3	(0.6)	4 0.6	3	(1.3)	5 1.6
No	5	(0.6)	6 0.6	4	(1.0)	5 1.0
Eye pruritus						
Yes	1	(0.2)	1 0.2	1	(0.4)	1 0.3
No	1	(0.1)	1 <0.1	0		
Conjunctivitis allergic						
Yes	1	(0.2)	1 0.2	0		
No	0			1	(0.2)	1 0.2
Eye allergy						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Ocular hyperaemia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Conjunctival irritation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eczema eyelids						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Eye discharge						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Meibomian gland dysfunction						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Swelling of eyelid						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Blepharitis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Conjunctival hyperaemia						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Erythema of eyelid						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Eye inflammation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.4)	2 0.7
No	0			0		
Eye irritation						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Keratitis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Ulcerative keratitis						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Anterior eye structural change, deposit and degeneration						
Yes	4	(0.8)	4 0.6	2	(0.9)	3 1.0
No	3	(0.4)	4 0.4	1	(0.2)	1 0.2
Cataract						
Yes	4	(0.8)	4 0.6	1	(0.4)	2 0.7
No	2	(0.2)	3 0.3	0		
Xerophthalmia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Ectropion						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Pterygium						
Yes	0			1	(0.4)	1 0.3
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Eye disorders NEC						
Yes	2 (0.4)	2	0.3	5 (2.1)	5	1.6
No	6 (0.7)	6	0.6	1 (0.2)	1	0.2
Dry eye						
Yes	2 (0.4)	2	0.3	3 (1.3)	3	1.0
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Eyelid disorder						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Eye pain						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Lacrimation increased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Ocular discomfort						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Glaucoma and ocular hypertension						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	2 (0.2)	2	0.2	0		
Glaucoma						
Yes	2 (0.4)	2	0.3	1 (0.4)	2	0.7
No	2 (0.2)	2	0.2	0		
Ocular structural change, deposit and degeneration NEC						
Yes	3 (0.6)	4	0.6	2 (0.9)	2	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Macular degeneration						
Yes	3	(0.6)	4 0.6	0		
No	0			0		
Vitreous detachment						
Yes	0			2	(0.9)	2 0.7
No	0			0		
Ocular haemorrhages and vascular disorders NEC						
Yes	1	(0.2)	1 0.2	0		
No	2	(0.2)	2 0.2	1	(0.2)	1 0.2
Optic ischaemic neuropathy						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Eyelid haematoma						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Conjunctival haemorrhage						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Retina, choroid and vitreous haemorrhages and vascular disorders						
Yes	2	(0.4)	2 0.3	0		
No	0			1	(0.2)	1 0.2
Retinopathy						
Yes	2	(0.4)	2 0.3	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Retinal aneurysm						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Ocular neuromuscular disorders						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Blepharospasm						
Yes	1 (0.2)	1	0.2	0		
No	0			1 (0.2)	1	0.2
Ocular sensory symptoms NEC						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Asthenopia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Renal and urinary disorders						
Yes	16 (3.4)	20	3.2	11 (4.7)	13	4.3
No	25 (3.0)	31	2.9	11 (2.6)	11	2.1
Urinary tract signs and symptoms						
Yes	9 (1.9)	9	1.4	6 (2.6)	7	2.3
No	17 (2.0)	20	1.9	2 (0.5)	2	0.4
Dysuria						
Yes	3 (0.6)	3	0.5	0		
No	6 (0.7)	8	0.7	0		
Haematuria						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			0		
Chromaturia						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Stress urinary incontinence						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Pollakiuria						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Renal pain						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Urine odour abnormal						
Yes	1	(0.2)	1 0.2	1	(0.4)	1 0.3
No	0			0		
Bladder pain						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Micturition urgency						
Yes	0			0		
No	1	(0.1)	1 <0.1	1	(0.2)	1 0.2
Nocturia						
Yes	0			2	(0.9)	2 0.7
No	1	(0.1)	1 <0.1	0		
Renal colic						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	2	0.2	0		
Urine flow decreased						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Polyuria						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Urinary incontinence						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Urinary retention						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Urolithiases						
Yes	5 (1.1)	6	0.9	2 (0.9)	2	0.7
No	6 (0.7)	6	0.6	4 (1.0)	4	0.8
Nephrolithiasis						
Yes	3 (0.6)	3	0.5	2 (0.9)	2	0.7
No	5 (0.6)	5	0.5	4 (1.0)	4	0.8
Calculus urinary						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Ureterolithiasis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Renal disorders (excl nephropathies)						
Yes	3 (0.6)	4	0.6	3 (1.3)	4	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	4 (0.5)	5	0.5	4 (1.0)	4	0.8
Acute kidney injury						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Renal cyst						
Yes	0			1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Chronic kidney disease						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			0		
Hydronephrosis						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Nephrectasia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Renal impairment						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Hypertensive nephropathy						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Bladder and bladder neck disorders (excl calculi)						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Cystitis noninfective						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Urethral disorders (excl calculi)						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Urethritis noninfective						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Ear and labyrinth disorders						
Yes	10 (2.1)	12	1.9	9 (3.8)	10	3.3
No	35 (4.2)	44	4.1	15 (3.6)	19	3.6
Inner ear and VIIIth cranial nerve disorders						
Yes	7 (1.5)	9	1.4	8 (3.4)	9	3.0
No	15 (1.8)	17	1.6	10 (2.4)	13	2.5
Vertigo						
Yes	6 (1.3)	6	0.9	7 (3.0)	8	2.6
No	11 (1.3)	11	1.0	5 (1.2)	5	1.0
Tinnitus						
Yes	2 (0.4)	3	0.5	0		
No	1 (0.1)	1	<0.1	2 (0.5)	3	0.6
Vertigo positional						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	4	0.4	2 (0.5)	3	0.6
Meniere's disease						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	1 (0.1)	1	<0.1	0		
Motion sickness						
Yes	0			0		
No	0			1 (0.2)	2	0.4
Aural disorders NEC						
Yes	2 (0.4)	2	0.3	0		
No	13 (1.6)	14	1.3	2 (0.5)	2	0.4
Ear pain						
Yes	1 (0.2)	1	0.2	0		
No	11 (1.3)	12	1.1	2 (0.5)	2	0.4
Ear discomfort						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Ear congestion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Middle ear disorders (excl congenital)						
Yes	1 (0.2)	1	0.2	0		
No	5 (0.6)	6	0.6	2 (0.5)	2	0.4
Eustachian tube dysfunction						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	4	0.4	1 (0.2)	1	0.2
Eustachian tube disorder						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Tympanic membrane disorder						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	0			1	(0.2)	1 0.2
Hearing disorders						
Yes	0			1	(0.4)	1 0.3
No	4	(0.5)	4 0.4	1	(0.2)	1 0.2
Deafness neurosensory						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Hypoacusis						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Sudden hearing loss						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Deafness						
Yes	0			1	(0.4)	1 0.3
No	0			0		
Hyperacusis						
Yes	0			0		
No	0			1	(0.2)	1 0.2
External ear disorders (excl congenital)						
Yes	0			0		
No	3	(0.4)	3 0.3	1	(0.2)	1 0.2
Cerumen impaction						
Yes	0			0		
No	3	(0.4)	3 0.3	0		
Excessive cerumen production						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hepatobiliary disorders						
Yes	10 (2.1)	12	1.9	4 (1.7)	4	1.3
No	34 (4.1)	44	4.1	9 (2.1)	10	1.9
Gallbladder disorders						
Yes	7 (1.5)	8	1.3	0		
No	24 (2.9)	30	2.8	5 (1.2)	5	1.0
Cholelithiasis						
Yes	4 (0.8)	4	0.6	0		
No	19 (2.3)	20	1.9	4 (1.0)	4	0.8
Gallbladder disorder						
Yes	3 (0.6)	3	0.5	0		
No	0			0		
Cholecystitis						
Yes	1 (0.2)	1	0.2	0		
No	3 (0.4)	3	0.3	1 (0.2)	1	0.2
Cholecystitis acute						
Yes	0			0		
No	4 (0.5)	4	0.4	0		
Cholecystitis chronic						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Biliary dyskinesia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hepatic and hepatobiliary disorders						
Yes	3 (0.6)	4	0.6	4 (1.7)	4	1.3
No	10 (1.2)	12	1.1	5 (1.2)	5	1.0
Hepatic steatosis						
Yes	2 (0.4)	2	0.3	4 (1.7)	4	1.3
No	4 (0.5)	4	0.4	3 (0.7)	3	0.6
Hepatic cyst						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Hepatic function abnormal						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Nonalcoholic fatty liver disease						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Granulomatous liver disease						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hepatic pain						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Hypertransaminasaemia						
Yes	0			0		
No	1 (0.1)	3	0.3	0		
Portal vein thrombosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Bile duct disorders						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Bile duct stone						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Biliary colic						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Blood and lymphatic system disorders						
Yes	16	(3.4)	17 2.7	5	(2.1)	7 2.3
No	19	(2.3)	20 1.9	11	(2.6)	14 2.7
Anaemias nonhaemolytic and marrow depression						
Yes	12	(2.5)	12 1.9	4	(1.7)	4 1.3
No	12	(1.4)	13 1.2	6	(1.4)	7 1.3
Anaemia						
Yes	9	(1.9)	9 1.4	3	(1.3)	3 1.0
No	10	(1.2)	11 1.0	6	(1.4)	7 1.3
Iron deficiency anaemia						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Blood loss anaemia						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Pernicious anaemia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Hypochromic anaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Pancytopenia						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Spleen, lymphatic and reticuloendothelial system disorders						
Yes	3 (0.6)	3	0.5	1 (0.4)	1	0.3
No	4 (0.5)	4	0.4	2 (0.5)	3	0.6
Lymphadenopathy						
Yes	2 (0.4)	2	0.3	0		
No	2 (0.2)	2	0.2	1 (0.2)	2	0.4
Splenomegaly						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	0			1 (0.2)	1	0.2
Hypersplenism						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Splenic haemorrhage						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
White blood cell disorders						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Leukocytosis						
Yes	1 (0.2)	1	0.2	1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Eosinophilia						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Platelet disorders						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Thrombocytopenia						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	3 (0.7)	3	0.6
Red blood cell disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Polycythaemia						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Microcytosis						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Immune system disorders						
Yes	12 (2.5)	12	1.9	6 (2.6)	7	2.3
No	16 (1.9)	16	1.5	15 (3.6)	16	3.0
Allergic conditions						
Yes	11 (2.3)	11	1.7	6 (2.6)	7	2.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R
No	16	(1.9)	16	1.5	15	(3.6)	16	3.0
Seasonal allergy								
Yes	6	(1.3)	6	0.9	5	(2.1)	5	1.6
No	9	(1.1)	9	0.8	9	(2.1)	9	1.7
Allergy to arthropod bite								
Yes	3	(0.6)	3	0.5	0			
No	0				0			
Hypersensitivity								
Yes	1	(0.2)	1	0.2	2	(0.9)	2	0.7
No	2	(0.2)	2	0.2	4	(1.0)	4	0.8
Drug hypersensitivity								
Yes	1	(0.2)	1	0.2	0			
No	1	(0.1)	1	<0.1	1	(0.2)	1	0.2
Food allergy								
Yes	0				0			
No	2	(0.2)	2	0.2	0			
Allergy to arthropod sting								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Rubber sensitivity								
Yes	0				0			
No	1	(0.1)	1	<0.1	0			
Mite allergy								
Yes	0				0			
No	0				1	(0.2)	1	0.2
Multiple allergies								
Yes	0				0			

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
No	0			1 (0.2)	1	0.2
Immune disorders NEC						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Immunisation reaction						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Surgical and medical procedures						
Yes	5 (1.1)	5	0.8	3 (1.3)	3	1.0
No	13 (1.6)	14	1.3	5 (1.2)	5	1.0
Head and neck therapeutic procedures						
Yes	4 (0.8)	4	0.6	0		
No	2 (0.2)	2	0.2	1 (0.2)	1	0.2
Dental operation						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Tooth extraction						
Yes	1 (0.2)	1	0.2	0		
No	1 (0.1)	1	<0.1	0		
Dental implantation						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Sinus operation						
Yes	1 (0.2)	1	0.2	0		
No	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Therapeutic procedures and supportive care NEC						
Yes	0			1	(0.4)	1 0.3
No	4	(0.5)	4 0.4	0		
Polypectomy						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Cyst removal						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Spinal anaesthesia						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Skin and subcutaneous tissue therapeutic procedures						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Acrochordon excision						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Skin neoplasm excision						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Eye therapeutic procedures						
Yes	1	(0.2)	1 0.2	0		
No	0			0		
Glaucoma surgery						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bone and joint therapeutic procedures						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Synovial cyst removal						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Bone prosthesis insertion						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hip surgery						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Gastrointestinal therapeutic procedures						
Yes	0			0		
No	1 (0.1)	1	<0.1	2 (0.5)	2	0.4
Gastric bypass						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Abdominoplasty						
Yes	0			0		
No	0			1 (0.2)	1	0.2
Hepatobiliary therapeutic procedures						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cholecystectomy						
Yes	0			0		
No	1 (0.1)	1	<0.1	1 (0.2)	1	0.2
Nervous system, skull and spine therapeutic procedures						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Intervertebral disc operation						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Obstetric and gynaecological therapeutic procedures						
Yes	0			1 (0.4)	1	0.3
No	1 (0.1)	1	<0.1	0		
Abortion induced						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Ovarian operation						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Soft tissue therapeutic procedures						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Lipoma excision						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Endocrine disorders						
Yes	5 (1.1)	6	0.9	3 (1.3)	3	1.0
No	9 (1.1)	10	0.9	3 (0.7)	4	0.8
Thyroid gland disorders						
Yes	5 (1.1)	6	0.9	3 (1.3)	3	1.0
No	8 (1.0)	9	0.8	3 (0.7)	3	0.6
Hypothyroidism						
Yes	2 (0.4)	2	0.3	1 (0.4)	1	0.3
No	2 (0.2)	2	0.2	3 (0.7)	3	0.6
Goitre						
Yes	2 (0.4)	2	0.3	0		
No	1 (0.1)	1	<0.1	0		
Hyperthyroidism						
Yes	1 (0.2)	1	0.2	0		
No	2 (0.2)	3	0.3	0		
Thyroid mass						
Yes	0			1 (0.4)	1	0.3
No	3 (0.4)	3	0.3	0		
Thyroid cyst						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Primary hyperthyroidism						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Adrenal gland disorders						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hyperadrenocorticism						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Endocrine disorders of gonadal function						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Hypogonadism						
Yes	0			0		
No	0			1	(0.2)	1 0.2
Social circumstances						
Yes	3	(0.6)	3 0.5	1	(0.4)	1 0.3
No	3	(0.4)	3 0.3	0		
Age related factors						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Menopause						
Yes	1	(0.2)	1 0.2	0		
No	1	(0.1)	1 <0.1	0		
Economic and housing issues						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Stress at work						
Yes	0			1	(0.4)	1 0.3
No	2	(0.2)	2 0.2	0		
Family issues						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Family stress						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Lifestyle issues						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Bedridden						
Yes	1 (0.2)	1	0.2	0		
No	0			0		
Pregnancy, puerperium and perinatal conditions						
Yes	0			0		
No	5 (0.6)	5	0.5	0		
Abortions and stillbirth						
Yes	0			0		
No	3 (0.4)	3	0.3	0		
Abortion spontaneous						
Yes	0			0		
No	2 (0.2)	2	0.2	0		
Abortion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Maternal complications of pregnancy						
Yes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
No	2	(0.2)	2 0.2	0		
Ectopic pregnancy						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Morning sickness						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Congenital, familial and genetic disorders						
Yes	0			1	(0.4)	1 0.3
No	4	(0.5)	4 0.4	0		
Metabolic and nutritional disorders congenital						
Yes	0			0		
No	3	(0.4)	3 0.3	0		
Type V hyperlipidaemia						
Yes	0			0		
No	2	(0.2)	2 0.2	0		
Gilbert's syndrome						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Musculoskeletal and connective tissue disorders congenital						
Yes	0			0		
No	1	(0.1)	1 <0.1	0		
Carpus curvus						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Skin and subcutaneous tissue disorders congenital						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Dermoid cyst						
Yes	0			1 (0.4)	1	0.3
No	0			0		
Product issues						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Device issues						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		
Device expulsion						
Yes	0			0		
No	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

39 Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Yes	284	377.4			275	362.3			286	373.4		
No	118	152.4			128	170.8			116	154.9		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Yes	230	(81.0)	1324	350.9	250	(90.9)	1516	418.5	219	(76.6)	1013	271.3
No	99	(83.9)	535	351.0	103	(80.5)	681	398.8	90	(77.6)	375	242.0
Serious												
Yes												
Yes	25	(8.8)	43	11.4	31	(11.3)	62	17.1	30	(10.5)	45	12.1
No	6	(5.1)	10	6.6	9	(7.0)	9	5.3	7	(6.0)	8	5.2
No												
Yes	228	(80.3)	1281	339.5	249	(90.5)	1454	401.4	217	(75.9)	968	259.2
No	98	(83.1)	525	344.4	103	(80.5)	672	393.5	90	(77.6)	367	236.9
Severity												
Severe												
Yes	14	(4.9)	34	9.0	24	(8.7)	47	13.0	23	(8.0)	33	8.8
No	8	(6.8)	9	5.9	3	(2.3)	4	2.3	5	(4.3)	6	3.9
Moderate												
Yes	96	(33.8)	227	60.2	125	(45.5)	335	92.5	89	(31.1)	203	54.4
No	39	(33.1)	88	57.7	48	(37.5)	173	101.3	29	(25.0)	61	39.4
Mild												
Yes	213	(75.0)	1063	281.7	228	(82.9)	1134	313.0	191	(66.8)	777	208.1
No	93	(78.8)	438	287.4	100	(78.1)	504	295.1	88	(75.9)	308	198.8

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Missing									
Yes	7 (2.5)	8	2.1	7 (2.5)	7	1.9	3 (1.0)	4	1.1
No	3 (2.5)	3	2.0	3 (2.3)	3	1.8	3 (2.6)	3	1.9
Probable									
Yes	84 (29.6)	198	52.5	111 (40.4)	269	74.3	41 (14.3)	70	18.7
No	49 (41.5)	146	95.8	58 (45.3)	187	109.5	21 (18.1)	30	19.4
Possible									
Yes	110 (38.7)	308	81.6	132 (48.0)	384	106.0	70 (24.5)	120	32.1
No	43 (36.4)	99	65.0	50 (39.1)	150	87.8	23 (19.8)	50	32.3
Unlikely									
Yes	207 (72.9)	810	214.7	216 (78.5)	856	236.3	206 (72.0)	819	219.3
No	89 (75.4)	287	188.3	85 (66.4)	341	199.7	83 (71.6)	292	188.5
Outcome									
Fatal									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Recovered									
Yes	220 (77.5)	1061	281.2	237 (86.2)	1218	336.2	201 (70.3)	756	202.5
No	95 (80.5)	442	290.0	96 (75.0)	594	347.8	84 (72.4)	298	192.3
Recovering									
Yes	14 (4.9)	26	6.9	13 (4.7)	22	6.1	12 (4.2)	12	3.2
No	5 (4.2)	6	3.9	4 (3.1)	4	2.3	5 (4.3)	7	4.5
Recovered With Sequelae									
Yes	5 (1.8)	5	1.3	4 (1.5)	4	1.1	0		
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Not Recovered									
Yes	105 (37.0)	232	61.5	117 (42.5)	264	72.9	112 (39.2)	243	65.1

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Outcome									
Not Recovered									
No	42 (35.6)	87	57.1	46 (35.9)	81	47.4	44 (37.9)	67	43.2
Unknown									
Yes	0			3 (1.1)	7	1.9	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Leading to									
Permanent treatment discontinuation									
Yes	12 (4.2)	15	4.0	20 (7.3)	27	7.5	12 (4.2)	16	4.3
No	8 (6.8)	8	5.2	5 (3.9)	7	4.1	2 (1.7)	2	1.3
Temporary interruption of trial product									
Yes	15 (5.3)	23	6.1	25 (9.1)	66	18.2	11 (3.8)	13	3.5
No	11 (9.3)	24	15.7	12 (9.4)	24	14.1	4 (3.4)	7	4.5
Dose reduction of trial product									
Yes	14 (4.9)	20	5.3	25 (9.1)	43	11.9	1 (0.3)	1	0.3
No	4 (3.4)	8	5.2	10 (7.8)	23	13.5	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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40 Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Yes	284		377.4		275		362.3		286		373.4	
No	118		152.4		128		170.8		116		154.9	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Yes	230	(81.0)	1324	350.9	250	(90.9)	1516	418.5	219	(76.6)	1013	271.3
No	99	(83.9)	535	351.0	103	(80.5)	681	398.8	90	(77.6)	375	242.0
Gastrointestinal disorders												
Yes	154	(54.2)	495	131.2	176	(64.0)	599	165.3	89	(31.1)	166	44.5
No	77	(65.3)	229	150.2	80	(62.5)	325	190.3	49	(42.2)	96	62.0
Gastrointestinal signs and symptoms												
Yes	124	(43.7)	278	73.7	134	(48.7)	392	108.2	52	(18.2)	73	19.6
No	63	(53.4)	154	101.0	66	(51.6)	209	122.4	24	(20.7)	42	27.1
Nausea												
Yes	81	(28.5)	126	33.4	92	(33.5)	162	44.7	24	(8.4)	25	6.7
No	48	(40.7)	72	47.2	44	(34.4)	87	50.9	13	(11.2)	20	12.9
Vomiting												
Yes	33	(11.6)	61	16.2	54	(19.6)	136	37.5	8	(2.8)	9	2.4
No	21	(17.8)	32	21.0	34	(26.6)	52	30.4	3	(2.6)	3	1.9
Dyspepsia												
Yes	23	(8.1)	23	6.1	11	(4.0)	15	4.1	3	(1.0)	3	0.8
No	4	(3.4)	4	2.6	14	(10.9)	15	8.8	2	(1.7)	2	1.3
Abdominal distension												
Yes	7	(2.5)	8	2.1	13	(4.7)	16	4.4	5	(1.7)	5	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	2 (1.7)	4	2.6	11 (8.6)	14	8.2	6 (5.2)	8	5.2
Flatulence									
Yes	14 (4.9)	15	4.0	9 (3.3)	14	3.9	6 (2.1)	7	1.9
No	7 (5.9)	10	6.6	7 (5.5)	7	4.1	1 (0.9)	2	1.3
Abdominal pain upper									
Yes	8 (2.8)	8	2.1	10 (3.6)	13	3.6	9 (3.1)	11	2.9
No	3 (2.5)	3	2.0	6 (4.7)	8	4.7	2 (1.7)	2	1.3
Eructation									
Yes	8 (2.8)	11	2.9	10 (3.6)	12	3.3	1 (0.3)	1	0.3
No	3 (2.5)	5	3.3	6 (4.7)	9	5.3	0		
Abdominal discomfort									
Yes	8 (2.8)	8	2.1	7 (2.5)	7	1.9	6 (2.1)	6	1.6
No	7 (5.9)	9	5.9	6 (4.7)	8	4.7	1 (0.9)	1	0.6
Abdominal pain									
Yes	9 (3.2)	10	2.7	8 (2.9)	10	2.8	4 (1.4)	4	1.1
No	8 (6.8)	10	6.6	5 (3.9)	5	2.9	1 (0.9)	1	0.6
Regurgitation									
Yes	0			2 (0.7)	2	0.6	0		
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Abdominal pain lower									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			2 (1.7)	2	1.3
Abnormal faeces									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Aerophagia									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.8)	1	0.6	0		
Gastrointestinal pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Epigastric discomfort									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal sounds abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Abdominal rigidity									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Anal incontinence									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Breath odour									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Dysphagia									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Faeces discoloured									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Faeces soft									
Yes	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			0		
Retching									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal motility and defaecation conditions									
Yes	90 (31.7)	185	49.0	97 (35.3)	159	43.9	45 (15.7)	64	17.1
No	35 (29.7)	58	38.1	46 (35.9)	80	46.8	25 (21.6)	37	23.9
Diarrhoea									
Yes	62 (21.8)	116	30.7	50 (18.2)	80	22.1	28 (9.8)	40	10.7
No	27 (22.9)	42	27.6	36 (28.1)	61	35.7	20 (17.2)	26	16.8
Constipation									
Yes	42 (14.8)	57	15.1	56 (20.4)	65	17.9	17 (5.9)	18	4.8
No	9 (7.6)	13	8.5	14 (10.9)	17	10.0	5 (4.3)	8	5.2
Gastrooesophageal reflux disease									
Yes	10 (3.5)	11	2.9	11 (4.0)	12	3.3	4 (1.4)	4	1.1
No	3 (2.5)	3	2.0	1 (0.8)	1	0.6	3 (2.6)	3	1.9
Change of bowel habit									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Gastrointestinal motility disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Irritable bowel syndrome									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal hypermotility									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Gastrooesophageal sphincter insufficiency									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal conditions NEC									
Yes	3 (1.1)	3	0.8	7 (2.5)	7	1.9	2 (0.7)	2	0.5
No	4 (3.4)	5	3.3	11 (8.6)	14	8.2	4 (3.4)	4	2.6
Hyperchlorhydria									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	0		
No	3 (2.5)	4	2.6	7 (5.5)	10	5.9	2 (1.7)	2	1.3
Food poisoning									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		
Gastrointestinal disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			2 (1.6)	2	1.2	0		
Barrett's oesophagus									
Yes	0			0			0		
No	0			0			2 (1.7)	2	1.3
Gastric disorder									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Gastrointestinal melanosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions									
Yes	4 (1.4)	4	1.1	8 (2.9)	10	2.8	5 (1.7)	7	1.9
No	5 (4.2)	5	3.3	9 (7.0)	10	5.9	1 (0.9)	1	0.6
Gastritis									
Yes	3 (1.1)	3	0.8	5 (1.8)	6	1.7	4 (1.4)	6	1.6
No	3 (2.5)	3	2.0	6 (4.7)	7	4.1	0		
Enteritis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			2 (1.6)	2	1.2	1 (0.9)	1	0.6
Enterocolitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Chronic gastritis									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Duodenitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Colitis									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Gastrointestinal vascular conditions									
Yes	3 (1.1)	5	1.3	7 (2.5)	7	1.9	2 (0.7)	2	0.5
No	0			2 (1.6)	2	1.2	0		
Haemorrhoids									
Yes	2 (0.7)	3	0.8	7 (2.5)	7	1.9	1 (0.3)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			2 (1.6)	2	1.2	0		
Haemorrhoids thrombosed									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Varices oesophageal									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Dental and gingival conditions									
Yes	3 (1.1)	3	0.8	9 (3.3)	9	2.5	3 (1.0)	3	0.8
No	5 (4.2)	6	3.9	1 (0.8)	2	1.2	4 (3.4)	4	2.6
Toothache									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	3 (2.5)	4	2.6	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Dental caries									
Yes	0			3 (1.1)	3	0.8	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	3 (2.6)	3	1.9
Gingival swelling									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Tooth deposit									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Periodontal disease									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Abdominal hernias and other abdominal wall conditions									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	4 (1.4)	4	1.1
No	0			2 (1.6)	2	1.2	1 (0.9)	1	0.6
Abdominal hernia									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Abdominal wall haematoma									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Hiatus hernia									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Umbilical hernia									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Inguinal hernia									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Salivary gland conditions									
Yes	1 (0.4)	1	0.3	2 (0.7)	3	0.8	0		
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	2 (1.7)	2	1.3
Dry mouth									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Parotid gland enlargement									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Salivary hypersecretion									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Noninfective sialoadenitis									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Gastrointestinal haemorrhages NEC									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.8	2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	0		
Haematochezia									
Yes	3 (1.1)	3	0.8	0			0		
No	0			1 (0.8)	1	0.6	0		
Intra-abdominal haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Mallory-Weiss syndrome									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Upper gastrointestinal haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Intra-abdominal haematoma									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Rectal haemorrhage									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Oral soft tissue conditions									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Mouth ulceration									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Stomatitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Aphthous ulcer									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Lip swelling									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Odynophagia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Benign neoplasms gastrointestinal									
Yes	5 (1.8)	6	1.6	3 (1.1)	3	0.8	2 (0.7)	2	0.5
No	0			0			2 (1.7)	2	1.3
Gastric polyps									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Large intestine polyp									
Yes	4 (1.4)	4	1.1	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Anal and rectal conditions NEC									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Anal fissure									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Diverticular disorders									
Yes	2 (0.7)	2	0.5	0			2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Diverticulum intestinal									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Diverticulum									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			1 (0.9)	1	0.6
Exocrine pancreas conditions									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Pancreatitis acute									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Obstructive pancreatitis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Pancreatic cyst									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal stenosis and obstruction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Small intestinal obstruction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal ulceration and perforation									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Gastritis erosive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diverticular perforation									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Gastric ulcer									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Malabsorption conditions									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Malabsorption									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Peritoneal and retroperitoneal conditions									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Retroperitoneal mass									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tongue conditions									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Glossodynia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Infections and infestations									
Yes	118 (41.5)	231	61.2	127 (46.2)	231	63.8	122 (42.7)	263	70.4
No	48 (40.7)	87	57.1	52 (40.6)	114	66.8	53 (45.7)	96	62.0
Infections - pathogen unspecified									
Yes	104 (36.6)	181	48.0	113 (41.1)	189	52.2	103 (36.0)	209	56.0
No	42 (35.6)	69	45.3	49 (38.3)	100	58.6	44 (37.9)	72	46.5
Nasopharyngitis									
Yes	36 (12.7)	55	14.6	44 (16.0)	70	19.3	39 (13.6)	64	17.1
No	11 (9.3)	14	9.2	24 (18.8)	45	26.3	20 (17.2)	28	18.1
Upper respiratory tract infection									
Yes	29 (10.2)	43	11.4	31 (11.3)	35	9.7	29 (10.1)	37	9.9
No	8 (6.8)	11	7.2	11 (8.6)	13	7.6	9 (7.8)	13	8.4
Urinary tract infection									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	7 (2.5)	8	2.1	7 (2.5)	10	2.8	9 (3.1)	11	2.9
No	10 (8.5)	13	8.5	6 (4.7)	6	3.5	3 (2.6)	5	3.2
Bronchitis									
Yes	7 (2.5)	8	2.1	9 (3.3)	10	2.8	8 (2.8)	9	2.4
No	3 (2.5)	3	2.0	5 (3.9)	6	3.5	5 (4.3)	6	3.9
Gastroenteritis									
Yes	19 (6.7)	19	5.0	9 (3.3)	10	2.8	8 (2.8)	10	2.7
No	5 (4.2)	9	5.9	5 (3.9)	5	2.9	5 (4.3)	5	3.2
Sinusitis									
Yes	3 (1.1)	3	0.8	11 (4.0)	15	4.1	11 (3.8)	13	3.5
No	3 (2.5)	3	2.0	3 (2.3)	4	2.3	0		
Conjunctivitis									
Yes	2 (0.7)	4	1.1	3 (1.1)	3	0.8	3 (1.0)	4	1.1
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Paronychia									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Pneumonia									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	3 (1.0)	3	0.8
No	0			2 (1.6)	3	1.8	2 (1.7)	2	1.3
Gastrointestinal infection									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	2 (1.6)	3	1.8	1 (0.9)	1	0.6
Pharyngitis									
Yes	0			1 (0.4)	1	0.3	6 (2.1)	6	1.6
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Cystitis									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.8	2 (0.7)	4	1.1
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Tonsillitis									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.8	3 (1.0)	3	0.8
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Lower respiratory tract infection									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	5 (1.7)	5	1.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Acute sinusitis									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	3 (1.0)	5	1.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Breast abscess									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Kidney infection									
Yes	0			0			2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	0		
Periodontitis									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	2	0.5
No	0			1 (0.8)	1	0.6	0		
Vulvovaginitis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	1 (0.8)	2	1.2	0		
Localised infection									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			0			0		
Otitis externa									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (1.1)	3	0.8	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	0			0		
Tooth infection									
Yes	3 (1.1)	4	1.1	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Abscess									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Appendicitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Chronic sinusitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diverticulitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			0			0		
Implant site infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Infected dermal cyst									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Mastitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Otitis media acute									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Post procedural infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Respiratory tract infection									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	5 (1.7)	5	1.3
No	0			0			0		
Rhinitis									
Yes	0			1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	0			0		
Skin infection									
Yes	0			1 (0.4)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Tooth abscess									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	1 (0.3)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Urosepsis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Colonic abscess									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Ear infection									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Empyema									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Eye infection									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Gingival abscess									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Gingivitis									
Yes	0			0			3 (1.0)	3	0.8
No	0			0			0		
Hordeolum									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.9)	1	0.6
Joint abscess									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Labyrinthitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Laryngitis									
Yes	2 (0.7)	3	0.8	0			0		
No	1 (0.8)	1	0.7	0			0		
Mastoiditis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Osteomyelitis									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Otitis media									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Otitis media chronic									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Pericoronitis									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Postoperative wound infection									
Yes	0			0			0		
No	1	(0.8)	1 0.7	0			0		
Pulpitis dental									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Pyelonephritis acute									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6
Sepsis									
Yes	3	(1.1)	3 0.8	0			0		
No	0			0			0		
Sialoadenitis									
Yes	0			0			0		
No	1	(0.8)	1 0.7	0			0		
Sinobronchitis									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Subcutaneous abscess									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Tracheitis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Tracheobronchitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Vaginal infection									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Wound infection									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Viral infectious disorders									
Yes	27 (9.5)	33	8.7	27 (9.8)	31	8.6	26 (9.1)	32	8.6
No	8 (6.8)	8	5.2	9 (7.0)	10	5.9	10 (8.6)	10	6.5
Influenza									
Yes	14 (4.9)	16	4.2	11 (4.0)	12	3.3	12 (4.2)	16	4.3
No	3 (2.5)	3	2.0	4 (3.1)	4	2.3	6 (5.2)	6	3.9
Gastroenteritis viral									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	5 (1.7)	5	1.3
No	2 (1.7)	2	1.3	2 (1.6)	3	1.8	2 (1.7)	2	1.3
Viral infection									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (1.1)	3	0.8	3 (1.1)	4	1.1	2 (0.7)	3	0.8
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Herpes zoster									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Herpes simplex									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Pneumonia influenzal									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Gastroenteritis norovirus									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Herpes virus infection									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ophthalmic herpes zoster									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Oral herpes									
Yes	2 (0.7)	3	0.8	1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Respiratory tract infection viral									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Viral diarrhoea									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Viral pharyngitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Chikungunya virus infection									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Ear infection viral									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Rhinovirus infection									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Viral upper respiratory tract infection									
Yes	2 (0.7)	3	0.8	0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Bacterial infectious disorders									
Yes	8 (2.8)	11	2.9	5 (1.8)	5	1.4	7 (2.4)	11	2.9
No	2 (1.7)	2	1.3	3 (2.3)	3	1.8	5 (4.3)	7	4.5
Cellulitis									
Yes	5 (1.8)	6	1.6	1 (0.4)	1	0.3	2 (0.7)	3	0.8
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Bacterial vaginosis									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ear infection bacterial									
Yes	1 (0.4)	3	0.8	0			0		
No	0			1 (0.8)	1	0.6	0		
Breast cellulitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Furuncle									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Pharyngitis streptococcal									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	2	0.5
No	1 (0.8)	1	0.7	0			2 (1.7)	2	1.3
Staphylococcal infection									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	3	0.8
No	0			0			0		
Clostridium difficile colitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Helicobacter gastritis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Helicobacter infection									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Wound infection staphylococcal									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Fungal infectious disorders									
Yes	6 (2.1)	6	1.6	6 (2.2)	6	1.7	8 (2.8)	10	2.7
No	8 (6.8)	8	5.2	1 (0.8)	1	0.6	7 (6.0)	7	4.5
Onychomycosis									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Fungal infection									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Fungal skin infection									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Tinea pedis									
Yes	0			1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			0			0		
Vulvovaginal candidiasis									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	3	0.8
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Vulvovaginal mycotic infection									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			2 (1.7)	2	1.3
Balanitis candida									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Candida infection									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dermatophytosis of nail									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Genital candidiasis									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Genital infection fungal									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Skin candida									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Tinea infection									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			2 (1.7)	2	1.3
Tinea versicolour									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Ectoparasitic disorders									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Acarodermatitis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Musculoskeletal and connective tissue disorders									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	73 (25.7)	111	29.4	70 (25.5)	107	29.5	69 (24.1)	104	27.9
No	26 (22.0)	36	23.6	28 (21.9)	44	25.8	15 (12.9)	22	14.2
Musculoskeletal and connective tissue disorders NEC									
Yes	42 (14.8)	48	12.7	39 (14.2)	44	12.1	25 (8.7)	29	7.8
No	15 (12.7)	18	11.8	17 (13.3)	22	12.9	8 (6.9)	9	5.8
Back pain									
Yes	20 (7.0)	22	5.8	19 (6.9)	21	5.8	11 (3.8)	11	2.9
No	8 (6.8)	8	5.2	8 (6.3)	9	5.3	3 (2.6)	4	2.6
Pain in extremity									
Yes	9 (3.2)	9	2.4	11 (4.0)	11	3.0	9 (3.1)	9	2.4
No	3 (2.5)	3	2.0	5 (3.9)	5	2.9	1 (0.9)	1	0.6
Musculoskeletal pain									
Yes	7 (2.5)	7	1.9	3 (1.1)	3	0.8	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	4 (3.1)	4	2.3	3 (2.6)	3	1.9
Neck pain									
Yes	1 (0.4)	1	0.3	5 (1.8)	5	1.4	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	3 (2.3)	3	1.8	0		
Musculoskeletal chest pain									
Yes	3 (1.1)	3	0.8	0			0		
No	2 (1.7)	3	2.0	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Flank pain									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Muscle contracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Neck mass									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Rheumatic disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Axillary mass									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Limb mass									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Musculoskeletal discomfort									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Musculoskeletal stiffness									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Plantar fasciitis									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Joint disorders									
Yes	29 (10.2)	36	9.5	34 (12.4)	42	11.6	35 (12.2)	42	11.2
No	9 (7.6)	10	6.6	10 (7.8)	15	8.8	6 (5.2)	7	4.5
Arthralgia									
Yes	16 (5.6)	18	4.8	18 (6.5)	21	5.8	18 (6.3)	18	4.8
No	8 (6.8)	9	5.9	5 (3.9)	8	4.7	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Osteoarthritis									
Yes	2 (0.7)	2	0.5	8 (2.9)	9	2.5	11 (3.8)	12	3.2
No	0			3 (2.3)	5	2.9	1 (0.9)	1	0.6
Rotator cuff syndrome									
Yes	4 (1.4)	6	1.6	2 (0.7)	3	0.8	0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Arthritis									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Periarthritis									
Yes	3 (1.1)	3	0.8	3 (1.1)	5	1.4	0		
No	0			0			1 (0.9)	1	0.6
Spinal osteoarthritis									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	6 (2.1)	6	1.6
No	0			0			0		
Joint swelling									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Arthritis climacteric									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Arthropathy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Femoroacetabular impingement									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gouty arthritis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Joint effusion									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Neuropathic arthropathy									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Psoriatic arthropathy									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Rheumatoid arthritis									
Yes	0			0			1 (0.3)	2	0.5
No	0			0			0		
Sacroiliitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Muscle disorders									
Yes	8 (2.8)	11	2.9	5 (1.8)	7	1.9	8 (2.8)	9	2.4
No	4 (3.4)	5	3.3	5 (3.9)	5	2.9	0		
Muscle spasms									
Yes	4 (1.4)	4	1.1	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	3 (2.5)	4	2.6	3 (2.3)	3	1.8	0		
Myalgia									
Yes	5 (1.8)	7	1.9	3 (1.1)	5	1.4	4 (1.4)	5	1.3
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diastasis recti abdominis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Muscular weakness									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Synovial and bursal disorders									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	0			2 (1.6)	2	1.2	3 (2.6)	4	2.6
Bursitis									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	0			2 (1.6)	2	1.2	3 (2.6)	4	2.6
Tendon, ligament and cartilage disorders									
Yes	6 (2.1)	6	1.6	5 (1.8)	5	1.4	8 (2.8)	9	2.4
No	0			0			1 (0.9)	1	0.6
Trigger finger									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Osteochondrosis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Tendon disorder									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Tendonitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	6 (2.1)	6	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Costochondritis									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Ligament calcification									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Meniscal degeneration									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tendon pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Bone disorders (excl congenital and fractures)									
Yes	3 (1.1)	3	0.8	3 (1.1)	4	1.1	3 (1.0)	3	0.8
No	3 (2.5)	3	2.0	0			1 (0.9)	1	0.6
Bone lesion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Exostosis									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Osteopenia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Osteoporosis									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Bone pain									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Metatarsalgia									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Osteitis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Yes	5 (1.8)	5	1.3	3 (1.1)	3	0.8	8 (2.8)	9	2.4
No	0			0			0		
Intervertebral disc protrusion									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.8	3 (1.0)	3	0.8
No	0			0			0		
Foot deformity									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	2	0.5
No	0			0			0		
Intervertebral disc degeneration									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Scoliosis									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Spinal flattening									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Spondylolisthesis									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Connective tissue disorders (excl congenital)									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Polymyalgia rheumatica									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Nervous system disorders									
Yes	35 (12.3)	66	17.5	62 (22.5)	93	25.7	49 (17.1)	71	19.0
No	28 (23.7)	39	25.6	20 (15.6)	25	14.6	14 (12.1)	21	13.6
Headaches									
Yes	21 (7.4)	35	9.3	23 (8.4)	30	8.3	16 (5.6)	19	5.1
No	15 (12.7)	21	13.8	14 (10.9)	16	9.4	8 (6.9)	13	8.4
Headache									
Yes	18 (6.3)	28	7.4	19 (6.9)	26	7.2	13 (4.5)	16	4.3
No	15 (12.7)	20	13.1	12 (9.4)	14	8.2	7 (6.0)	11	7.1
Migraine									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	0		
No	0			1 (0.8)	1	0.6	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Migraine with aura									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Tension headache									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Occipital neuralgia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Sinus headache									
Yes	1 (0.4)	2	0.5	0			1 (0.3)	1	0.3
No	0			0			0		
Neurological disorders NEC									
Yes	19 (6.7)	22	5.8	30 (10.9)	40	11.0	24 (8.4)	31	8.3
No	9 (7.6)	11	7.2	6 (4.7)	6	3.5	7 (6.0)	7	4.5
Dizziness									
Yes	11 (3.9)	13	3.4	17 (6.2)	18	5.0	12 (4.2)	14	3.7
No	7 (5.9)	8	5.2	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Dysgeusia									
Yes	0			2 (0.7)	6	1.7	1 (0.3)	1	0.3
No	0			2 (1.6)	2	1.2	0		
Paraesthesia									
Yes	2 (0.7)	2	0.5	4 (1.5)	6	1.7	4 (1.4)	5	1.3
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Somnolence									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hypoaesthesia									
Yes	0			3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Dizziness postural									
Yes	0			2 (0.7)	2	0.6	0		
No	1 (0.8)	2	1.3	0			0		
Hyperaesthesia									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			0			0		
Syncope									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Ageusia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Aphasia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Coordination abnormal									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Dysaesthesia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Head discomfort									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hypogeusia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Lethargy									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Loss of consciousness									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Neuralgia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Phantom limb syndrome									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Presyncope									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Restless legs syndrome									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Central nervous system vascular disorders									
Yes	2 (0.7)	2	0.5	7 (2.5)	9	2.5	2 (0.7)	3	0.8
No	0			1 (0.8)	2	1.2	0		
Carotid arteriosclerosis									
Yes	0			1 (0.4)	1	0.3	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.8)	1	0.6	0		
Carotid artery stenosis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Cerebrovascular accident									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Cerebral artery stenosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cerebral artery thrombosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cerebral infarction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Spinal epidural haematoma									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Subarachnoid haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ischaemic stroke									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	2	0.5
No	0			0			0		
Spinal cord and nerve root disorders									
Yes	2 (0.7)	2	0.5	2 (0.7)	3	0.8	4 (1.4)	4	1.1

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	3 (2.5)	3	2.0	1 (0.8)	1	0.6	0		
Sciatica									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	0		
Radiculopathy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Sacral radiculopathy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cervical radiculopathy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cervicobrachial syndrome									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Lumbar radiculopathy									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			0		
Peripheral neuropathies									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	7 (2.4)	8	2.1
No	3 (2.5)	4	2.6	0			0		
Carpal tunnel syndrome									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	2	1.3	0			0		
Diabetic neuropathy									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			0		
Meralgia paraesthetica									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Neuropathy peripheral									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	3	0.8
No	0			0			0		
Nerve compression									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Polyneuropathy									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Cranial nerve disorders (excl neoplasms)									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Anosmia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Facial paralysis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Encephalopathies									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Hepatic encephalopathy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hyponatraemic encephalopathy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Mental impairment disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			0			1 (0.9)	1	0.6
Memory impairment									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Amnesia									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.9)	1	0.6
Dementia Alzheimer's type									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Vascular dementia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Sleep disturbances (incl subtypes)									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hypersomnia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Structural brain disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cerebral ventricle dilatation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Movement disorders (incl parkinsonism)									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Tremor									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Neurological disorders of the eye									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Visual field defect									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Seizures (incl subtypes)									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Partial seizures									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
General disorders and administration site conditions									
Yes	41 (14.4)	56	14.8	52 (18.9)	70	19.3	34 (11.9)	44	11.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	10 (8.5)	13	8.5	17 (13.3)	23	13.5	12 (10.3)	17	11.0
General system disorders NEC									
Yes	34 (12.0)	44	11.7	46 (16.7)	54	14.9	22 (7.7)	24	6.4
No	6 (5.1)	8	5.2	11 (8.6)	14	8.2	6 (5.2)	6	3.9
Fatigue									
Yes	15 (5.3)	21	5.6	22 (8.0)	22	6.1	4 (1.4)	4	1.1
No	4 (3.4)	5	3.3	6 (4.7)	7	4.1	0		
Asthenia									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	0			3 (2.3)	4	2.3	0		
Influenza like illness									
Yes	1 (0.4)	1	0.3	4 (1.5)	5	1.4	3 (1.0)	3	0.8
No	0			1 (0.8)	1	0.6	0		
Pain									
Yes	4 (1.4)	4	1.1	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Early satiety									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	0			0			0		
Malaise									
Yes	1 (0.4)	2	0.5	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	0			0			0		
Non-cardiac chest pain									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.8	0		
No	0			0			0		
Thirst decreased									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.8)	1	0.6	0		
Oedema peripheral									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	3 (1.0)	3	0.8
No	0			0			1 (0.9)	1	0.6
Peripheral swelling									
Yes	0			2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	0			0			2 (1.7)	2	1.3
Chest discomfort									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Chest pain									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	4	1.1
No	0			0			0		
Face oedema									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Feeling cold									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hunger									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Swelling									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Chills									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			0		
Discomfort									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Inflammation									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Polyp									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Sensation of foreign body									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Thirst									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Administration site reactions									
Yes	2 (0.7)	3	0.8	7 (2.5)	12	3.3	9 (3.1)	15	4.0
No	4 (3.4)	4	2.6	6 (4.7)	7	4.1	1 (0.9)	3	1.9
Injection site pain									
Yes	1 (0.4)	1	0.3	4 (1.5)	6	1.7	2 (0.7)	6	1.6
No	3 (2.5)	3	2.0	3 (2.3)	3	1.8	1 (0.9)	1	0.6
Injection site erythema									
Yes	0			0			0		
No	0			3 (2.3)	3	1.8	0		
Injection site reaction									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.8)	1	0.6	0		
Injection site bruising									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	0			1 (0.9)	2	1.3
Implant site pain									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Injection site mass									
Yes	0			1 (0.4)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Injection site discomfort									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Injection site haemorrhage									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Injection site urticaria									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Body temperature conditions									
Yes	8 (2.8)	8	2.1	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	5 (4.3)	8	5.2
Pyrexia									
Yes	8 (2.8)	8	2.1	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	5 (4.3)	8	5.2
Therapeutic and nontherapeutic effects (excl toxicity)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Drug intolerance									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Tissue disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Mass									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Nodule									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Complications associated with device									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Complication associated with device									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Metabolism and nutrition disorders									
Yes	39 (13.7)	55	14.6	38 (13.8)	45	12.4	34 (11.9)	42	11.2
No	9 (7.6)	13	8.5	18 (14.1)	21	12.3	19 (16.4)	19	12.3
Appetite and general nutritional disorders									
Yes	28 (9.9)	32	8.5	26 (9.5)	28	7.7	10 (3.5)	12	3.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	4 (3.4)	8	5.2	15 (11.7)	18	10.5	6 (5.2)	6	3.9
Decreased appetite									
Yes	25 (8.8)	28	7.4	25 (9.1)	27	7.5	9 (3.1)	11	2.9
No	4 (3.4)	6	3.9	13 (10.2)	14	8.2	6 (5.2)	6	3.9
Hyperphagia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Increased appetite									
Yes	3 (1.1)	3	0.8	0			0		
No	1 (0.8)	2	1.3	1 (0.8)	1	0.6	0		
Overweight									
Yes	0			0			0		
No	0			1 (0.8)	2	1.2	0		
Cachexia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Obesity									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lipid metabolism disorders									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	3 (2.5)	3	2.0	2 (1.6)	2	1.2	5 (4.3)	5	3.2
Dyslipidaemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	4 (3.4)	4	2.6
Hyperlipidaemia									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Hypertriglyceridaemia									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Hypercholesterolaemia									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Electrolyte and fluid balance conditions									
Yes	6 (2.1)	7	1.9	7 (2.5)	7	1.9	3 (1.0)	3	0.8
No	0			0			0		
Dehydration									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.8	2 (0.7)	2	0.5
No	0			0			0		
Hypokalaemia									
Yes	2 (0.7)	3	0.8	3 (1.1)	3	0.8	0		
No	0			0			0		
Hyponatraemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Hyperkalaemia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Purine and pyrimidine metabolism disorders									
Yes	2 (0.7)	3	0.8	1 (0.4)	1	0.3	3 (1.0)	5	1.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gout									
Yes	2 (0.7)	3	0.8	1 (0.4)	1	0.3	2 (0.7)	4	1.1
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Hyperuricaemia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Vitamin related disorders									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			0			1 (0.9)	1	0.6
Folate deficiency									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vitamin B complex deficiency									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Vitamin D deficiency									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Acid-base disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Ketoacidosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Lactic acidosis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bone, calcium, magnesium and phosphorus metabolism disorders									
Yes	4 (1.4)	4	1.1	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			0			1 (0.9)	1	0.6
Hypomagnesaemia									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Hypercalcaemia									
Yes	2 (0.7)	2	0.5	0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Hypercalcitoninaemia									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Hypocalcaemia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Diabetic complications									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Diabetic ketoacidosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Diabetic metabolic decompensation									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Glucose metabolism disorders (incl diabetes mellitus)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	2 (0.7)	3	0.8	1 (0.4)	1	0.3	14 (4.9)	14	3.7
No	1 (0.8)	1	0.7	0			6 (5.2)	6	3.9
Diabetes mellitus									
Yes	0			1 (0.4)	1	0.3	4 (1.4)	4	1.1
No	0			0			2 (1.7)	2	1.3
Diabetes mellitus inadequate control									
Yes	1 (0.4)	2	0.5	0			5 (1.7)	5	1.3
No	0			0			0		
Hyperglycaemia									
Yes	0			0			3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	0			2 (1.7)	2	1.3
Hyperinsulinaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hypoglycaemia									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Type 2 diabetes mellitus									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.9)	1	0.6
Iron and trace metal metabolism disorders									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Iron deficiency									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolism disorders NEC									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Hyperamylasaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hyperlipasaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Eye disorders									
Yes	32 (11.3)	47	12.5	32 (11.6)	45	12.4	29 (10.1)	40	10.7
No	14 (11.9)	18	11.8	18 (14.1)	24	14.1	13 (11.2)	16	10.3
Retina, choroid and vitreous haemorrhages and vascular disorders									
Yes	7 (2.5)	8	2.1	11 (4.0)	13	3.6	8 (2.8)	9	2.4
No	5 (4.2)	5	3.3	10 (7.8)	10	5.9	3 (2.6)	3	1.9
Diabetic retinopathy									
Yes	7 (2.5)	8	2.1	9 (3.3)	10	2.8	8 (2.8)	9	2.4
No	4 (3.4)	4	2.6	6 (4.7)	6	3.5	3 (2.6)	3	1.9
Non-proliferative retinopathy									
Yes	0			0			0		
No	0			2 (1.6)	2	1.2	0		
Retinopathy hypertensive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Retinal artery occlusion									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Retinal haemorrhage									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Retinopathy									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Anterior eye structural change, deposit and degeneration									
Yes	5 (1.8)	5	1.3	5 (1.8)	6	1.7	9 (3.1)	12	3.2
No	3 (2.5)	3	2.0	4 (3.1)	5	2.9	3 (2.6)	3	1.9
Cataract									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	6 (2.1)	7	1.9
No	1 (0.8)	1	0.7	1 (0.8)	2	1.2	2 (1.7)	2	1.3
Cataract cortical									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Cataract subcapsular									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Dermatochalasis									
Yes	0			0			2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Narrow anterior chamber angle									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cataract nuclear									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Pinguecula									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Posterior capsule opacification									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Ocular infections, irritations and inflammations									
Yes	10 (3.5)	10	2.7	4 (1.5)	6	1.7	3 (1.0)	3	0.8
No	3 (2.5)	3	2.0	4 (3.1)	4	2.3	3 (2.6)	3	1.9
Macular oedema									
Yes	1 (0.4)	1	0.3	1 (0.4)	2	0.6	0		
No	0			1 (0.8)	1	0.6	0		
Eyelid rash									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Meibomian gland dysfunction									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Ocular hyperaemia									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Blepharitis									
Yes	3 (1.1)	3	0.8	2 (0.7)	3	0.8	1 (0.3)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (0.9)	1	0.6
Keratitis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Conjunctivitis allergic									
Yes	2 (0.7)	2	0.5	0			0		
No	1 (0.8)	1	0.7	0			0		
Episcleritis									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Eye pruritus									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Punctate keratitis									
Yes	0			0			0		
No	2 (1.7)	2	1.3	0			0		
Swelling of eyelid									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Uveitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Eye disorders NEC									
Yes	7 (2.5)	7	1.9	6 (2.2)	6	1.7	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	3 (2.6)	3	1.9
Dry eye									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	3 (1.0)	3	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	2 (1.7)	2	1.3
Lacrimation increased									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Vitreous disorder									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Eyelid disorder									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Retinal disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Yes	8 (2.8)	10	2.7	5 (1.8)	5	1.4	3 (1.0)	4	1.1
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	0		
Optic disc disorder									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Detachment of retinal pigment epithelium									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Macular fibrosis									
Yes	1 (0.4)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retinal degeneration									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Retinal depigmentation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vitreous detachment									
Yes	1 (0.4)	2	0.5	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Age-related macular degeneration									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Choroidal dystrophy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Macular degeneration									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Optic atrophy									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Retinal drusen									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Vitreous floaters									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vision disorders									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	5 (1.7)	5	1.3
No	4 (3.4)	4	2.6	1 (0.8)	1	0.6	3 (2.6)	3	1.9
Vision blurred									
Yes	3 (1.1)	3	0.8	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Myopia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Visual impairment									
Yes	0			1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Astigmatism									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			1 (0.9)	1	0.6
Hypermetropia									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Pathologic myopia									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Presbyopia									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Ocular sensory symptoms NEC									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Asthenopia									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Glaucoma and ocular hypertension									
Yes	1 (0.4)	1	0.3	2 (0.7)	3	0.8	2 (0.7)	2	0.5
No	0			0			0		
Glaucoma									
Yes	1 (0.4)	1	0.3	2 (0.7)	3	0.8	2 (0.7)	2	0.5
No	0			0			0		
Ocular haemorrhages and vascular disorders NEC									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Eye haemorrhage									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Conjunctival haemorrhage									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.9)	1	0.6
Optic disc haemorrhage									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Ocular neuromuscular disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Eyelid ptosis									
Yes	0			1 (0.4)	1	0.3	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Injury, poisoning and procedural complications									
Yes	37 (13.0)	50	13.3	32 (11.6)	50	13.8	34 (11.9)	43	11.5
No	14 (11.9)	21	13.8	16 (12.5)	18	10.5	15 (12.9)	18	11.6
Injuries NEC									
Yes	27 (9.5)	33	8.7	21 (7.6)	28	7.7	27 (9.4)	31	8.3
No	10 (8.5)	16	10.5	11 (8.6)	11	6.4	9 (7.8)	9	5.8
Muscle strain									
Yes	4 (1.4)	4	1.1	5 (1.8)	5	1.4	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	3 (2.3)	3	1.8	0		
Limb injury									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		
Fall									
Yes	7 (2.5)	7	1.9	5 (1.8)	6	1.7	2 (0.7)	3	0.8
No	1 (0.8)	1	0.7	0			0		
Skin laceration									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Bone contusion									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Ligament sprain									
Yes	4 (1.4)	5	1.3	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	2 (1.7)	3	2.0	0			2 (1.7)	2	1.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Animal bite									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Epicondylitis									
Yes	0			0			1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	0		
Muscle injury									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Skin abrasion									
Yes	0			0			0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Contusion									
Yes	0			2 (0.7)	3	0.8	7 (2.4)	8	2.1
No	0			0			1 (0.9)	1	0.6
Arthropod sting									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Face injury									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Head injury									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Post-traumatic pain									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Road traffic accident									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Tooth fracture									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	0			1 (0.9)	1	0.6
Traumatic haemothorax									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Abdominal injury									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Arthropod bite									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Chest injury									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Craniocerebral injury									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Foreign body in eye									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Injury corneal									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ligament rupture									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Muscle rupture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Post-traumatic neck syndrome									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Soft tissue injury									
Yes	4 (1.4)	4	1.1	0			0		
No	1 (0.8)	1	0.7	0			0		
Spinal column injury									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Subdural haematoma									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Tendon injury									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Tendon rupture									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Wound									
Yes	0			0			3 (1.0)	3	0.8
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bone and joint injuries									
Yes	5 (1.8)	6	1.6	10 (3.6)	14	3.9	7 (2.4)	7	1.9
No	3 (2.5)	3	2.0	4 (3.1)	5	2.9	6 (5.2)	6	3.9
Rib fracture									
Yes	0			2 (0.7)	2	0.6	0		
No	0			2 (1.6)	2	1.2	0		
Foot fracture									
Yes	0			3 (1.1)	3	0.8	0		
No	0			1 (0.8)	1	0.6	3 (2.6)	3	1.9
Stress fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Wrist fracture									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Humerus fracture									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			0			0		
Cervical vertebral fracture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Joint injury									
Yes	0			1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	0			2 (1.7)	2	1.3
Meniscus injury									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Radius fracture												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Spinal compression fracture												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Thoracic vertebral fracture												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Upper limb fracture												
Yes	0				1	(0.4)	1	0.3	0			
No	0				0				0			
Ankle fracture												
Yes	0				0				0			
No	1	(0.8)	1	0.7	0				0			
Bone fissure												
Yes	0				0				0			
No	1	(0.8)	1	0.7	0				0			
Cartilage injury												
Yes	1	(0.4)	1	0.3	0				0			
No	0				0				0			
Hand fracture												
Yes	0				0				0			
No	0				0				1	(0.9)	1	0.6
Hip fracture												
Yes	1	(0.4)	1	0.3	0				0			
No	0				0				0			

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Joint dislocation									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Lisfranc fracture									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Spinal fracture									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Sternal fracture									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Procedural related injuries and complications NEC									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	4 (1.4)	4	1.1
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Post procedural haemorrhage									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Anaemia postoperative									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Graft complication									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Procedural pain									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Dental restoration failure									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Incision site pain									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Post procedural complication									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Surgical skin tear									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Medication errors and other product use errors and issues									
Yes	5 (1.8)	8	2.1	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	2	1.3
Accidental overdose									
Yes	3 (1.1)	5	1.3	0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	2	1.3
Extra dose administered									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dose calculation error									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Incorrect dose administered									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Injuries by physical agents									
Yes	0			3 (1.1)	3	0.8	0		
No	2 (1.7)	2	1.3	0			0		
Hypobarism									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Sunburn									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thermal burn									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Heat illness									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Overdoses and underdoses NEC									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Intentional overdose									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Yes	30 (10.6)	37	9.8	38 (13.8)	47	13.0	29 (10.1)	36	9.6

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	6 (5.1)	7	4.6	9 (7.0)	15	8.8	7 (6.0)	7	4.5
Respiratory disorders NEC									
Yes	15 (5.3)	16	4.2	12 (4.4)	12	3.3	12 (4.2)	15	4.0
No	1 (0.8)	1	0.7	6 (4.7)	7	4.1	3 (2.6)	3	1.9
Cough									
Yes	9 (3.2)	10	2.7	7 (2.5)	7	1.9	6 (2.1)	7	1.9
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Pulmonary mass									
Yes	1 (0.4)	1	0.3	0			0		
No	0			3 (2.3)	3	1.8	0		
Productive cough									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			1 (0.8)	1	0.6	0		
Respiratory disorder									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			1 (0.8)	1	0.6	0		
Acute respiratory failure									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Sleep apnoea syndrome									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			2 (1.7)	2	1.3
Dyspnoea									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Hypoxia									
Yes	0			0			1 (0.3)	1	0.3

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Respiratory tract signs and symptoms									
Yes	11 (3.9)	11	2.9	15 (5.5)	15	4.1	8 (2.8)	8	2.1
No	2 (1.7)	2	1.3	4 (3.1)	4	2.3	1 (0.9)	1	0.6
Oropharyngeal pain									
Yes	8 (2.8)	8	2.1	7 (2.5)	7	1.9	5 (1.7)	5	1.3
No	0			0			1 (0.9)	1	0.6
Rhinorrhoea									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	0		
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		
Oropharyngeal discomfort									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Upper respiratory tract congestion									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Dysphonia									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Aphonia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dry throat									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hiccups									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			0		
Painful respiration									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Nasal discomfort									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Upper-airway cough syndrome									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Upper respiratory tract disorders (excl infections)									
Yes	4 (1.4)	4	1.1	9 (3.3)	11	3.0	7 (2.4)	8	2.1
No	2 (1.7)	3	2.0	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Rhinitis allergic									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			1 (0.8)	1	0.6	0		
Epistaxis									
Yes	1 (0.4)	1	0.3	4 (1.5)	5	1.4	4 (1.4)	4	1.1
No	0			0			1 (0.9)	1	0.6
Nasal congestion									
Yes	0			2 (0.7)	2	0.6	2 (0.7)	3	0.8
No	2 (1.7)	3	2.0	0			0		
Sinus congestion									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Bronchial disorders (excl neoplasms)									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	4 (1.4)	4	1.1	5 (1.8)	6	1.7	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	2 (1.6)	3	1.8	2 (1.7)	2	1.3
Asthma									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	1 (0.8)	2	1.2	1 (0.9)	1	0.6
Bronchospasm									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Chronic obstructive pulmonary disease									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Childhood asthma									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lower respiratory tract disorders (excl obstruction and infection)									
Yes	1 (0.4)	2	0.5	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Atelectasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Idiopathic interstitial pneumonia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Emphysema									
Yes	1 (0.4)	1	0.3	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Pleural disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Pneumothorax									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Skin and subcutaneous tissue disorders									
Yes	26 (9.2)	29	7.7	29 (10.5)	38	10.5	29 (10.1)	33	8.8
No	12 (10.2)	14	9.2	11 (8.6)	16	9.4	8 (6.9)	9	5.8
Epidermal and dermal conditions									
Yes	15 (5.3)	16	4.2	22 (8.0)	27	7.5	17 (5.9)	18	4.8
No	8 (6.8)	9	5.9	5 (3.9)	8	4.7	5 (4.3)	5	3.2
Rash									
Yes	3 (1.1)	3	0.8	6 (2.2)	9	2.5	3 (1.0)	3	0.8
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Eczema									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Dry skin									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Blister									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	2	1.2	0		
Rash pruritic									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Pruritus									
Yes	1 (0.4)	1	0.3	0			3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Skin lesion									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Decubitus ulcer									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis allergic									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis contact									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Drug eruption									
Yes	0			1 (0.4)	1	0.3	3 (1.0)	4	1.1
No	1 (0.8)	1	0.7	0			0		
Intertrigo									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Pain of skin									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Perioral dermatitis									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Psoriasis									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Sensitive skin									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Skin burning sensation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Skin exfoliation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis									
Yes	2 (0.7)	2	0.5	0			2 (0.7)	2	0.5
No	0			0			0		
Erythema									
Yes	1 (0.4)	2	0.5	0			0		
No	0			0			0		
Neurodermatitis									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Parapsoriasis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Rash erythematous									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.9)	1	0.6
Stasis dermatitis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Xanthelasma									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Skin appendage conditions									
Yes	8 (2.8)	8	2.1	4 (1.5)	5	1.4	5 (1.7)	5	1.3
No	3 (2.5)	3	2.0	5 (3.9)	7	4.1	3 (2.6)	3	1.9
Alopecia									
Yes	3 (1.1)	3	0.8	3 (1.1)	4	1.1	0		
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	2 (1.7)	2	1.3
Acne									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Alopecia areata									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Hyperhidrosis									
Yes	1 (0.4)	1	0.3	0			3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	1 (0.8)	2	1.2	0		
Onychomadesis									
Yes	0			0			0		
No	0			1 (0.8)	2	1.2	0		
Ingrowing nail									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Miliaria									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			1 (0.9)	1	0.6
Nail dystrophy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Angioedema and urticaria									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Urticaria									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Chronic spontaneous urticaria									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cornification and dystrophic skin disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Actinic keratosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Dermatitis papillaris capillitii									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperkeratosis									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Punctate keratosis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Cutaneous neoplasms benign									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	4	1.1
No	0			0			0		
Dermal cyst									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	4	1.1
No	0			0			0		
Skin and subcutaneous tissue disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	4	1.1	2 (0.7)	2	0.5
No	0			0			0		
Diabetic foot									
Yes	0			1 (0.4)	3	0.8	0		
No	0			0			0		
Skin ulcer									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			0			0		
Skin vascular abnormalities									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Ecchymosis									
Yes	1 (0.4)	1	0.3	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Haemorrhage subcutaneous									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Investigations									
Yes	13 (4.6)	17	4.5	36 (13.1)	43	11.9	23 (8.0)	31	8.3
No	5 (4.2)	6	3.9	4 (3.1)	5	2.9	10 (8.6)	11	7.1
Cardiac and vascular investigations (excl enzyme tests)									
Yes	2 (0.7)	2	0.5	7 (2.5)	8	2.2	3 (1.0)	3	0.8
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Heart rate increased									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Blood pressure decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Blood pressure increased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cardiac murmur									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Cardiac stress test abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Carotid pulse decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Electrocardiogram Q waves									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Electrocardiogram QT prolonged									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Electrocardiogram PR prolongation									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Electrocardiogram ST-T segment abnormal									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Renal and urinary tract investigations and urinalyses									
Yes	0			4 (1.5)	4	1.1	0		
No	0			2 (1.6)	2	1.2	0		
Glomerular filtration rate decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			2 (1.6)	2	1.2	0		
Urine albumin/creatinine ratio increased									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urine albumin/creatinine ratio abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal investigations									
Yes	4 (1.4)	4	1.1	6 (2.2)	6	1.7	3 (1.0)	4	1.1
No	1 (0.8)	1	0.7	0			0		
Lipase increased									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.8	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Colonoscopy normal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Occult blood									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Occult blood positive									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Amylase increased									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Faecal volume increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Pancreatic enzymes increased									
Yes	0			0			1 (0.3)	1	0.3

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Hepatobiliary investigations									
Yes	3 (1.1)	4	1.1	2 (0.7)	2	0.6	5 (1.7)	8	2.1
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Hepatic enzyme increased									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Liver function test abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Liver function test increased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Alanine aminotransferase increased									
Yes	1 (0.4)	1	0.3	0			4 (1.4)	4	1.1
No	0			0			0		
Aspartate aminotransferase increased									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			0		
Blood bilirubin increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Transaminases increased									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Endocrine investigations (incl sex hormones)									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Blood thyroid stimulating hormone decreased									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Blood thyroid stimulating hormone increased									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	0			0			0		
Blood parathyroid hormone increased									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Haematology investigations (incl blood groups)									
Yes	0			4 (1.5)	6	1.7	1 (0.3)	1	0.3
No	0			0			0		
Haemoglobin decreased									
Yes	0			3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			0			0		
Haematocrit decreased									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Platelet count decreased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Enzyme investigations NEC									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Blood creatine phosphokinase increased									
Yes	1 (0.4)	1	0.3	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Physical examination and organ system status topics									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Weight decreased									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Weight increased									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lipid analyses									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Lipids abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Low density lipoprotein increased									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Blood cholesterol increased									
Yes	0			0			1 (0.3)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Blood triglycerides increased									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Investigations, imaging and histopathology procedures NEC									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Endoscopy abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Metabolic, nutritional and blood gas investigations									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	5 (1.7)	6	1.6
No	1 (0.8)	1	0.7	0			3 (2.6)	3	1.9
Vitamin B12 decreased									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Blood glucose decreased									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Blood glucose increased									
Yes	0			0			3 (1.0)	3	0.8
No	0			0			1 (0.9)	1	0.6
Blood uric acid increased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Brain natriuretic peptide increased									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Glycosylated haemoglobin increased									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			2 (1.7)	2	1.3
Microbiology and serology investigations									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Helicobacter test positive									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Neurological, special senses and psychiatric investigations									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Intraocular pressure increased									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			0		
Protein and chemistry analyses NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
C-reactive protein increased									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Reproductive organ and breast investigations (excl hormone analyses)									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Mammogram abnormal									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Water, electrolyte and mineral investigations									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Blood potassium increased									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Blood potassium decreased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Blood sodium increased									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Cytogenetic investigations									
Yes	0			0			0		
No	0			0			2 (1.7)	2	1.3
Prostatic specific antigen increased									
Yes	0			0			0		
No	0			0			2 (1.7)	2	1.3
Immunology and allergy investigations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Antinuclear antibody increased									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Renal and urinary disorders									
Yes	15 (5.3)	17	4.5	25 (9.1)	30	8.3	23 (8.0)	25	6.7
No	4 (3.4)	5	3.3	6 (4.7)	7	4.1	5 (4.3)	9	5.8
Urinary tract signs and symptoms									
Yes	6 (2.1)	6	1.6	15 (5.5)	15	4.1	12 (4.2)	12	3.2
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	4 (3.4)	7	4.5
Dysuria									
Yes	0			2 (0.7)	2	0.6	3 (1.0)	3	0.8
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Haematuria									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Microalbuminuria									
Yes	3 (1.1)	3	0.8	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	0			0			0		
Nocturia									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Proteinuria									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Renal colic									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			1 (0.9)	1	0.6
Pollakiuria									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Lower urinary tract symptoms									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Micturition disorder									
Yes	0			0			0		
No	0			0			1 (0.9)	2	1.3
Polyuria									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Urethral pain									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Urinary incontinence									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Nephropathies									
Yes	3 (1.1)	3	0.8	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			3 (2.3)	3	1.8	0		
Diabetic nephropathy									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			2 (1.6)	2	1.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nephropathy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Renal disorders (excl nephropathies)									
Yes	3 (1.1)	3	0.8	5 (1.8)	7	1.9	7 (2.4)	7	1.9
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	0		
Renal cyst									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Acute kidney injury									
Yes	2 (0.7)	2	0.5	3 (1.1)	4	1.1	2 (0.7)	2	0.5
No	0			0			0		
Chronic kidney disease									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Renal impairment									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hydronephrosis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Kidney fibrosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Urolithiases									
Yes	4 (1.4)	5	1.3	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	2 (1.7)	2	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nephrolithiasis									
Yes	4 (1.4)	5	1.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Calculus urinary									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Stag horn calculus									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ureterolithiasis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Bladder and bladder neck disorders (excl calculi)									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Bladder outlet obstruction									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hypertonic bladder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Bladder hypertrophy									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Vascular disorders									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	19 (6.7)	20	5.3	14 (5.1)	15	4.1	26 (9.1)	28	7.5
No	3 (2.5)	3	2.0	10 (7.8)	11	6.4	4 (3.4)	4	2.6
Vascular hypertensive disorders									
Yes	8 (2.8)	8	2.1	6 (2.2)	7	1.9	12 (4.2)	13	3.5
No	1 (0.8)	1	0.7	4 (3.1)	4	2.3	3 (2.6)	3	1.9
Hypertension									
Yes	8 (2.8)	8	2.1	6 (2.2)	7	1.9	9 (3.1)	9	2.4
No	1 (0.8)	1	0.7	4 (3.1)	4	2.3	3 (2.6)	3	1.9
Hypertensive crisis									
Yes	0			0			3 (1.0)	3	0.8
No	0			0			0		
Hypertensive urgency									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Vascular disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			2 (1.6)	2	1.2	1 (0.9)	1	0.6
Aortic dilatation									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Hot flush									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Aortic rupture									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Decreased and nonspecific blood pressure disorders and shock									
Yes	5 (1.8)	6	1.6	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	0			1 (0.8)	2	1.2	0		
Orthostatic hypotension									
Yes	0			0			2 (0.7)	2	0.5
No	0			1 (0.8)	2	1.2	0		
Hypotension									
Yes	4 (1.4)	5	1.3	2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	0			0			0		
Blood pressure inadequately controlled									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Shock									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Vascular haemorrhagic disorders									
Yes	0			3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			0			0		
Haematoma									
Yes	0			3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			0			0		
Aneurysms and artery dissections									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Aortic aneurysm									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Yes	5 (1.8)	5	1.3	0			5 (1.7)	6	1.6
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Aortic arteriosclerosis									
Yes	3 (1.1)	3	0.8	0			0		
No	0			1 (0.8)	1	0.6	0		
Arteriosclerosis									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Peripheral arterial occlusive disease									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Peripheral artery stenosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Peripheral coldness									
Yes	1 (0.4)	1	0.3	0			0		
No	1 (0.8)	1	0.7	0			0		
Peripheral venous disease									
Yes	0			0			2 (0.7)	3	0.8
No	0			0			0		
Vascular infections and inflammations									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (0.8)	1	0.6	0		
Temporal arteritis									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Embolism and thrombosis									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Post thrombotic syndrome									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Deep vein thrombosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lymphatic vessel disorders									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lymphoedema									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Venous varices									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Varicose vein									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Psychiatric disorders									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	16 (5.6)	21	5.6	16 (5.8)	20	5.5	7 (2.4)	7	1.9
No	7 (5.9)	7	4.6	8 (6.3)	9	5.3	8 (6.9)	9	5.8
Sleep disorders and disturbances									
Yes	4 (1.4)	4	1.1	5 (1.8)	5	1.4	3 (1.0)	3	0.8
No	2 (1.7)	2	1.3	5 (3.9)	5	2.9	1 (0.9)	1	0.6
Insomnia									
Yes	4 (1.4)	4	1.1	4 (1.5)	4	1.1	3 (1.0)	3	0.8
No	2 (1.7)	2	1.3	3 (2.3)	3	1.8	1 (0.9)	1	0.6
Middle insomnia									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Sleep disorder									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Abnormal dreams									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Depressed mood disorders and disturbances									
Yes	3 (1.1)	3	0.8	5 (1.8)	5	1.4	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	2 (1.6)	2	1.2	3 (2.6)	3	1.9
Depressed mood									
Yes	2 (0.7)	2	0.5	2 (0.7)	2	0.6	0		
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		
Depression									
Yes	0			2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	0			3 (2.6)	3	1.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Anhedonia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Major depression									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Anxiety disorders and symptoms									
Yes	8 (2.8)	9	2.4	4 (1.5)	4	1.1	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	4 (3.4)	4	2.6
Anxiety									
Yes	5 (1.8)	6	1.6	2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	2 (1.7)	2	1.3
Anxiety disorder due to a general medical condition									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Stress									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Generalised anxiety disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Nervousness									
Yes	2 (0.7)	2	0.5	0			0		
No	0			0			0		
Post-traumatic stress disorder									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (0.9)	1	0.6
Adjustment disorders (incl subtypes)									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Grief reaction									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Adjustment disorder with depressed mood									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Mood disorders and disturbances NEC									
Yes	1 (0.4)	1	0.3	2 (0.7)	3	0.8	0		
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Irritability									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Mood altered									
Yes	0			1 (0.4)	2	0.6	0		
No	0			0			1 (0.9)	1	0.6
Mood swings									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Changes in physical activity									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Restlessness									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Suicidal and self-injurious behaviours NEC									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Suicidal ideation									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Psychiatric disorders NEC									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Mental status changes									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Sexual dysfunctions, disturbances and gender identity disorders									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Libido decreased									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cardiac disorders									
Yes	14 (4.9)	18	4.8	17 (6.2)	22	6.1	10 (3.5)	14	3.7
No	6 (5.1)	6	3.9	5 (3.9)	6	3.5	3 (2.6)	3	1.9
Cardiac arrhythmias									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	7 (2.5)	9	2.4	11 (4.0)	14	3.9	2 (0.7)	3	0.8
No	3 (2.5)	3	2.0	2 (1.6)	2	1.2	2 (1.7)	2	1.3
Atrial fibrillation									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Supraventricular extrasystoles									
Yes	0			4 (1.5)	4	1.1	0		
No	0			0			0		
Bundle branch block right									
Yes	0			0			0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Tachycardia									
Yes	1 (0.4)	1	0.3	2 (0.7)	2	0.6	0		
No	0			0			0		
Atrioventricular block first degree									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Sinus tachycardia									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Supraventricular tachycardia									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Ventricular extrasystoles									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Atrial flutter									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			1 (0.3)	2	0.5
No	0			0			0		
Bradycardia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Bundle branch block left									
Yes	2 (0.7)	2	0.5	0			0		
No	1 (0.8)	1	0.7	0			0		
Coronary artery disorders									
Yes	6 (2.1)	6	1.6	6 (2.2)	6	1.7	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Angina pectoris									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	2	0.5
No	0			1 (0.8)	1	0.6	0		
Acute myocardial infarction									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Angina unstable									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Coronary artery disease									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Myocardial infarction									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Myocardial ischaemia									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Arteriosclerosis coronary artery									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Cardiac disorders, signs and symptoms NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	2 (1.7)	2	1.3	2 (1.6)	3	1.8	1 (0.9)	1	0.6
Palpitations									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Cardiovascular disorder									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	2	1.2	0		
Hypertensive heart disease									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Heart failures									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.7)	3	0.8
No	0			0			0		
Cardiac failure congestive									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Cardiac failure acute									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Left ventricular failure									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Myocardial disorders									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Cardiac hypertrophy									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Left ventricular hypertrophy									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Ear and labyrinth disorders									
Yes	8 (2.8)	10	2.7	17 (6.2)	17	4.7	7 (2.4)	7	1.9
No	3 (2.5)	4	2.6	3 (2.3)	3	1.8	5 (4.3)	7	4.5
Inner ear and VIIIth cranial nerve disorders									
Yes	6 (2.1)	8	2.1	9 (3.3)	9	2.5	4 (1.4)	4	1.1
No	2 (1.7)	3	2.0	1 (0.8)	1	0.6	4 (3.4)	5	3.2
Vertigo									
Yes	2 (0.7)	3	0.8	6 (2.2)	6	1.7	2 (0.7)	2	0.5
No	1 (0.8)	2	1.3	1 (0.8)	1	0.6	4 (3.4)	5	3.2
Vertigo positional									
Yes	0			3 (1.1)	3	0.8	1 (0.3)	1	0.3
No	0			0			0		
Motion sickness									

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	2	0.5	0			0		
No	1 (0.8)	1	0.7	0			0		
Tinnitus									
Yes	3 (1.1)	3	0.8	0			1 (0.3)	1	0.3
No	0			0			0		
Aural disorders NEC									
Yes	1 (0.4)	1	0.3	5 (1.8)	5	1.4	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Ear pain									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Ear pruritus									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Ear discomfort									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Hearing disorders									
Yes	0			2 (0.7)	2	0.6	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Hypoacusis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			1 (0.8)	1	0.6	0		
Deafness bilateral									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Deafness unilateral									

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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Mixed deafness									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
External ear disorders (excl congenital)									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Cerumen impaction									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Excessive cerumen production									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Reproductive system and breast disorders									
Yes	8 (2.8)	9	2.4	6 (2.2)	6	1.7	7 (2.4)	9	2.4
No	7 (5.9)	11	7.2	6 (4.7)	6	3.5	2 (1.7)	2	1.3
Menstrual cycle and uterine bleeding disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.3)	2	0.5
No	1 (0.8)	1	0.7	2 (1.6)	2	1.2	0		
Metrorrhagia									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Oligomenorrhoea									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Dysmenorrhoea									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Menorrhagia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Menstruation irregular									
Yes	0			0			1 (0.3)	2	0.5
No	1 (0.8)	1	0.7	0			0		
Vulvovaginal disorders (excl infections and inflammations)									
Yes	0			2 (0.7)	2	0.6	2 (0.7)	2	0.5
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Vulva cyst									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Vulval disorder									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vulvovaginal pruritus									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Vaginal disorder									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vaginal haemorrhage									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Vulvovaginal dryness									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Sexual function and fertility disorders									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Erectile dysfunction									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Menopause related conditions									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Atrophic vulvovaginitis									
Yes	0			0			1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	0		
Uterine, pelvic and broad ligament disorders									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Uterine polyp									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Adenomyosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Endometriosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Breast disorders									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Breast mass									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	0			0			0		
Breast cyst									
Yes	0			0			0		
No	0			0			1 (0.9)	1	0.6
Breast pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Reproductive tract disorders NEC									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Pruritus genital									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Pelvic pain									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Male reproductive tract infections and inflammations									
Yes	2 (0.7)	2	0.5	0			1 (0.3)	1	0.3
No	2 (1.7)	2	1.3	0			0		
Balanoposthitis									
Yes	2 (0.7)	2	0.5	0			0		
No	1 (0.8)	1	0.7	0			0		
Prostatitis									
Yes	0			0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Ovarian and fallopian tube disorders									
Yes	0			0			0		
No	2 (1.7)	2	1.3	0			0		
Haemorrhagic ovarian cyst									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Ovarian cyst									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Penile and scrotal disorders (excl infections and inflammations)									
Yes	0			0			0		
No	1 (0.8)	2	1.3	0			0		
Penile erosion									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Peyronie's disease									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Prostatic disorders (excl infections and inflammations)									
Yes	2 (0.7)	2	0.5	0			1 (0.3)	1	0.3
No	0			0			0		
Benign prostatic hyperplasia									
Yes	2 (0.7)	2	0.5	0			1 (0.3)	1	0.3
No	0			0			0		
Testicular and epididymal disorders									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Testicular disorder									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Blood and lymphatic system disorders									
Yes	4 (1.4)	4	1.1	9 (3.3)	10	2.8	9 (3.1)	10	2.7
No	5 (4.2)	5	3.3	3 (2.3)	3	1.8	1 (0.9)	1	0.6
Anaemias nonhaemolytic and marrow depression									
Yes	3 (1.1)	3	0.8	7 (2.5)	8	2.2	5 (1.7)	5	1.3
No	5 (4.2)	5	3.3	3 (2.3)	3	1.8	1 (0.9)	1	0.6
Anaemia									
Yes	1 (0.4)	1	0.3	7 (2.5)	7	1.9	3 (1.0)	3	0.8
No	3 (2.5)	3	2.0	2 (1.6)	2	1.2	1 (0.9)	1	0.6
Iron deficiency anaemia									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Pancytopenia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Hypochromic anaemia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Microcytic anaemia									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Normocytic anaemia									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Platelet disorders									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thrombocytosis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
Yes	0			1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	0			0			0		
Splenomegaly									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lymphadenopathy									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
White blood cell disorders									
Yes	1 (0.4)	1	0.3	0			2 (0.7)	2	0.5
No	0			0			0		
Leukocytosis									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Lymphopenia									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Hepatobiliary disorders									
Yes	5 (1.8)	6	1.6	7 (2.5)	9	2.5	8 (2.8)	13	3.5
No	5 (4.2)	5	3.3	3 (2.3)	4	2.3	1 (0.9)	1	0.6
Hepatic and hepatobiliary disorders									
Yes	3 (1.1)	3	0.8	6 (2.2)	6	1.7	8 (2.8)	9	2.4
No	3 (2.5)	3	2.0	2 (1.6)	3	1.8	1 (0.9)	1	0.6
Hepatic steatosis									
Yes	2 (0.7)	2	0.5	3 (1.1)	3	0.8	4 (1.4)	4	1.1
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	1 (0.9)	1	0.6
Hepatic lesion									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Nonalcoholic fatty liver disease									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Hepatic cyst									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Non-alcoholic steatohepatitis									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Portal vein thrombosis									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			0			0		
Drug-induced liver injury									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Hepatic cirrhosis									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Hepatomegaly									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Liver disorder									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Portal hypertension									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Gallbladder disorders									
Yes	2 (0.7)	3	0.8	2 (0.7)	3	0.8	3 (1.0)	4	1.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	2 (1.7)	2	1.3	1 (0.8)	1	0.6	0		
Gallbladder polyp									
Yes	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	1 (0.8)	1	0.6	0		
Cholecystitis chronic									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cholelithiasis									
Yes	2 (0.7)	2	0.5	1 (0.4)	1	0.3	3 (1.0)	3	0.8
No	1 (0.8)	1	0.7	0			0		
Cholecystitis acute									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Yes	10 (3.5)	13	3.4	8 (2.9)	9	2.5	9 (3.1)	11	2.9
No	3 (2.5)	3	2.0	1 (0.8)	1	0.6	3 (2.6)	3	1.9
Gastrointestinal neoplasms benign									
Yes	3 (1.1)	4	1.1	1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	0			1 (0.8)	1	0.6	1 (0.9)	1	0.6
Gastrointestinal tract adenoma									
Yes	0			0			0		
No	0			1 (0.8)	1	0.6	0		
Benign duodenal neoplasm									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Colon adenoma									
Yes	3 (1.1)	4	1.1	0			1 (0.3)	1	0.3
No	0			0			1 (0.9)	1	0.6
Leukaemias									
Yes	0			2 (0.7)	2	0.6	0		
No	0			0			0		
Chronic lymphocytic leukaemia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Myeloid leukaemia									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Cutaneous neoplasms benign									
Yes	0			1 (0.4)	1	0.3	1 (0.3)	1	0.3
No	1 (0.8)	1	0.7	0			0		
Anogenital warts									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			0		
Melanocytic naevus									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Lymphomas non-Hodgkin's unspecified histology									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Gastrointestinal lymphoma									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Miscellaneous and site unspecified neoplasms malignant and unspecified									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Squamous cell carcinoma									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Yes	0			1	(0.4)	1 0.3	1	(0.3)	1 0.3
No	0			0			0		
Nasal cavity cancer									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Keratinising squamous cell carcinoma of nasopharynx									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Skeletal neoplasms benign									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Osteochondroma									
Yes	0			1	(0.4)	1 0.3	0		
No	0			0			0		
Soft tissue neoplasms benign									
Yes	0			1	(0.4)	1 0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Lipoma									
Yes	0			1 (0.4)	1	0.3	0		
No	1 (0.8)	1	0.7	0			1 (0.9)	1	0.6
Breast neoplasms malignant and unspecified (incl nipple)									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Invasive ductal breast carcinoma									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Endocrine neoplasms benign									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Pituitary tumour benign									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Endocrine neoplasms malignant and unspecified									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Neuroendocrine tumour									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Gastrointestinal neoplasms malignant and unspecified									
Yes	5 (1.8)	5	1.3	0			2 (0.7)	2	0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Adenocarcinoma gastric									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Adenocarcinoma of colon									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Gastric cancer									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Gastric cancer stage IV									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Gastrointestinal stromal tumour									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Gastrointestinal submucosal tumour									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Oral neoplasm									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Hepatobiliary neoplasms malignant and unspecified									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Hepatocellular carcinoma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Metastases									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Metastases to liver									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms female benign									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Uterine leiomyoma									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms female malignant and unspecified									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Uterine cancer									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Reproductive neoplasms male malignant and unspecified									
Yes	0			0			2	(0.7)	2 0.5
No	0			0			1	(0.9)	1 0.6
Prostate cancer									
Yes	0			0			2	(0.7)	2 0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (0.9)	1	0.6
Skin neoplasms malignant and unspecified									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Basal cell carcinoma									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Immune system disorders									
Yes	6 (2.1)	6	1.6	5 (1.8)	5	1.4	4 (1.4)	5	1.3
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Allergic conditions									
Yes	5 (1.8)	5	1.3	5 (1.8)	5	1.4	4 (1.4)	5	1.3
No	0			1 (0.8)	1	0.6	2 (1.7)	2	1.3
Seasonal allergy									
Yes	2 (0.7)	2	0.5	4 (1.5)	4	1.1	3 (1.0)	4	1.1
No	0			0			1 (0.9)	1	0.6
Hypersensitivity									
Yes	1 (0.4)	1	0.3	0			0		
No	0			1 (0.8)	1	0.6	0		
Allergy to arthropod sting									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			1 (0.9)	1	0.6
Allergy to chemicals									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Drug hypersensitivity									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Multiple allergies									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Immune disorders NEC									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Immunisation reaction									
Yes	1 (0.4)	1	0.3	0			0		
No	0			0			0		
Endocrine disorders									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	4 (1.4)	4	1.1
No	2 (1.7)	2	1.3	0			0		
Thyroid gland disorders									
Yes	1 (0.4)	1	0.3	4 (1.5)	4	1.1	4 (1.4)	4	1.1
No	2 (1.7)	2	1.3	0			0		
Hypothyroidism									
Yes	0			2 (0.7)	2	0.6	0		
No	1 (0.8)	1	0.7	0			0		
Primary hyperthyroidism									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thyroid cyst									
Yes	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Autoimmune thyroiditis									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Goitre									
Yes	0			0			1 (0.3)	1	0.3
No	0			0			0		
Silent thyroiditis									
Yes	0			0			0		
No	1 (0.8)	1	0.7	0			0		
Thyroid mass									
Yes	0			0			2 (0.7)	2	0.5
No	0			0			0		
Surgical and medical procedures									
Yes	3 (1.1)	3	0.8	1 (0.4)	1	0.3	4 (1.4)	5	1.3
No	0			0			1 (0.9)	1	0.6
Endocrine gland therapeutic procedures									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Thyroidectomy									
Yes	0			1 (0.4)	1	0.3	0		
No	0			0			0		
Bone and joint therapeutic procedures									
Yes	1 (0.4)	1	0.3	0			1 (0.3)	1	0.3
No	0			0			0		
Bone graft									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Joint injection									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Cardiac therapeutic procedures									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Cardiac pacemaker replacement									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Eye therapeutic procedures									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Cataract operation									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Head and neck therapeutic procedures									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Tooth extraction									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Male genital tract therapeutic procedures									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Sperm aspiration									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6
Therapeutic procedures and supportive care NEC									
Yes	0			0			3	(1.0)	3 0.8
No	0			0			0		
Cyst removal									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Nerve block									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Stent placement									
Yes	0			0			1	(0.3)	1 0.3
No	0			0			0		
Congenital, familial and genetic disorders									
Yes	1	(0.4)	1 0.3	0			2	(0.7)	2 0.5
No	0			0			0		
Reproductive tract and breast disorders congenital									
Yes	0			0			2	(0.7)	2 0.5
No	0			0			0		
Phimosis									
Yes	0			0			2	(0.7)	2 0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			0		
Respiratory disorders congenital									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Laryngeal web									
Yes	1	(0.4)	1 0.3	0			0		
No	0			0			0		
Pregnancy, puerperium and perinatal conditions									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6
Abortions and stillbirth									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6
Abortion spontaneous									
Yes	0			0			0		
No	0			0			1	(0.9)	1 0.6
Social circumstances									
Yes	1	(0.4)	1 0.3	0			0		
No	1	(0.8)	1 0.7	0			0		
Economic and housing issues									
Yes	1	(0.4)	1 0.3	0			0		
No	1	(0.8)	1 0.7	0			0		
Stress at work									
Yes	1	(0.4)	1 0.3	0			0		
No	1	(0.8)	1 0.7	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

41 Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Yes	73	102.9			152	208.9			73	101.9		
No	27	33.3			47	66.1			28	39.9		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Yes	60	(82.2)	377	366.5	130	(85.5)	613	293.4	56	(76.7)	156	153.0
No	22	(81.5)	106	318.0	41	(87.2)	221	334.2	24	(85.7)	79	198.0
Serious												
Yes												
Yes	4	(5.5)	7	6.8	10	(6.6)	12	5.7	7	(9.6)	7	6.9
No	3	(11.1)	3	9.0	0				0			
No												
Yes	60	(82.2)	370	359.7	129	(84.9)	601	287.7	54	(74.0)	149	146.2
No	22	(81.5)	103	309.0	41	(87.2)	221	334.2	24	(85.7)	79	198.0
Severity												
Severe												
Yes	2	(2.7)	2	1.9	3	(2.0)	4	1.9	4	(5.5)	4	3.9
No	1	(3.7)	1	3.0	0				1	(3.6)	1	2.5
Moderate												
Yes	12	(16.4)	57	55.4	20	(13.2)	32	15.3	6	(8.2)	6	5.9
No	2	(7.4)	6	18.0	5	(10.6)	10	15.1	5	(17.9)	7	17.5
Mild												
Yes	57	(78.1)	318	309.1	128	(84.2)	577	276.2	53	(72.6)	146	143.2
No	22	(81.5)	99	297.0	40	(85.1)	211	319.1	23	(82.1)	71	177.9

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Missing									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Probable									
Yes	18 (24.7)	50	48.6	37 (24.3)	109	52.2	9 (12.3)	15	14.7
No	7 (25.9)	11	33.0	18 (38.3)	49	74.1	1 (3.6)	1	2.5
Possible									
Yes	41 (56.2)	157	152.6	63 (41.4)	144	68.9	5 (6.8)	7	6.9
No	14 (51.9)	33	99.0	21 (44.7)	62	93.8	5 (17.9)	10	25.1
Unlikely									
Yes	53 (72.6)	170	165.2	114 (75.0)	359	171.9	51 (69.9)	134	131.5
No	20 (74.1)	62	186.0	38 (80.9)	110	166.4	23 (82.1)	68	170.4
Outcome									
Recovered									
Yes	58 (79.5)	321	312.0	124 (81.6)	528	252.8	52 (71.2)	125	122.6
No	20 (74.1)	88	264.0	40 (85.1)	201	304.0	23 (82.1)	61	152.9
Recovering									
Yes	8 (11.0)	15	14.6	13 (8.6)	17	8.1	4 (5.5)	4	3.9
No	1 (3.7)	1	3.0	3 (6.4)	4	6.0	1 (3.6)	1	2.5
Not Recovered									
Yes	24 (32.9)	41	39.9	43 (28.3)	68	32.6	17 (23.3)	27	26.5
No	11 (40.7)	17	51.0	11 (23.4)	16	24.2	9 (32.1)	17	42.6
Leading to									
Permanent treatment discontinuation									
Yes	1 (1.4)	1	1.0	5 (3.3)	9	4.3	1 (1.4)	1	1.0
No	2 (7.4)	5	15.0	0			0		

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by hypertension at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Leading to									
Temporary interruption of trial product									
Yes	5 (6.8)	6	5.8	11 (7.2)	16	7.7	4 (5.5)	4	3.9
No	2 (7.4)	3	9.0	3 (6.4)	10	15.1	1 (3.6)	1	2.5
Dose reduction of trial product									
Yes	3 (4.1)	3	2.9	10 (6.6)	14	6.7	0		
No	0			4 (8.5)	5	7.6	0		

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

42 Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Yes	73		102.9		152		208.9		73		101.9	
No	27		33.3		47		66.1		28		39.9	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Yes	60	(82.2)	377	366.5	130	(85.5)	613	293.4	56	(76.7)	156	153.0
No	22	(81.5)	106	318.0	41	(87.2)	221	334.2	24	(85.7)	79	198.0
Gastrointestinal disorders												
Yes	48	(65.8)	215	209.0	90	(59.2)	242	115.8	21	(28.8)	33	32.4
No	16	(59.3)	41	123.0	28	(59.6)	101	152.7	9	(32.1)	10	25.1
Gastrointestinal motility and defaecation conditions												
Yes	32	(43.8)	72	70.0	59	(38.8)	90	43.1	7	(9.6)	7	6.9
No	9	(33.3)	12	36.0	19	(40.4)	29	43.9	2	(7.1)	2	5.0
Constipation												
Yes	17	(23.3)	20	19.4	40	(26.3)	48	23.0	1	(1.4)	1	1.0
No	2	(7.4)	2	6.0	12	(25.5)	12	18.1	2	(7.1)	2	5.0
Diarrhoea												
Yes	15	(20.5)	49	47.6	24	(15.8)	36	17.2	6	(8.2)	6	5.9
No	7	(25.9)	10	30.0	8	(17.0)	16	24.2	0			
Gastrooesophageal reflux disease												
Yes	2	(2.7)	2	1.9	5	(3.3)	5	2.4	0			
No	0				1	(2.1)	1	1.5	0			
Gastrointestinal motility disorder												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Irritable bowel syndrome									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Gastrointestinal signs and symptoms									
Yes	25 (34.2)	124	120.5	52 (34.2)	107	51.2	9 (12.3)	15	14.7
No	14 (51.9)	27	81.0	19 (40.4)	62	93.8	2 (7.1)	2	5.0
Nausea									
Yes	13 (17.8)	21	20.4	25 (16.4)	46	22.0	3 (4.1)	3	2.9
No	5 (18.5)	6	18.0	10 (21.3)	20	30.2	1 (3.6)	1	2.5
Vomiting									
Yes	6 (8.2)	30	29.2	11 (7.2)	17	8.1	2 (2.7)	2	2.0
No	4 (14.8)	4	12.0	6 (12.8)	12	18.1	0		
Abdominal pain									
Yes	2 (2.7)	3	2.9	6 (3.9)	6	2.9	0		
No	1 (3.7)	1	3.0	6 (12.8)	10	15.1	0		
Abdominal pain upper									
Yes	1 (1.4)	2	1.9	5 (3.3)	8	3.8	1 (1.4)	1	1.0
No	2 (7.4)	3	9.0	5 (10.6)	5	7.6	0		
Dyspepsia									
Yes	5 (6.8)	16	15.6	4 (2.6)	6	2.9	1 (1.4)	4	3.9
No	1 (3.7)	1	3.0	5 (10.6)	8	12.1	0		
Abdominal discomfort									
Yes	6 (8.2)	7	6.8	10 (6.6)	13	6.2	0		
No	5 (18.5)	5	15.0	2 (4.3)	3	4.5	1 (3.6)	1	2.5
Abdominal distension									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	5 (6.8)	5	4.9	6 (3.9)	6	2.9	2 (2.7)	3	2.9
No	2 (7.4)	3	9.0	1 (2.1)	2	3.0	0		
Faeces soft									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			1 (2.1)	1	1.5	0		
Abdominal tenderness									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Eructation									
Yes	3 (4.1)	20	19.4	2 (1.3)	2	1.0	0		
No	1 (3.7)	1	3.0	0			0		
Faeces hard									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Flatulence									
Yes	1 (1.4)	18	17.5	1 (0.7)	1	0.5	0		
No	0			0			0		
Abdominal pain lower									
Yes	0			0			1 (1.4)	2	2.0
No	1 (3.7)	2	6.0	0			0		
Epigastric discomfort									
Yes	1 (1.4)	1	1.0	0			0		
No	1 (3.7)	1	3.0	0			0		
Dental and gingival conditions									
Yes	5 (6.8)	5	4.9	10 (6.6)	11	5.3	4 (5.5)	4	3.9
No	1 (3.7)	1	3.0	4 (8.5)	4	6.0	2 (7.1)	2	5.0
Dental caries									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	3 (4.1)	3	2.9	10 (6.6)	11	5.3	3 (4.1)	3	2.9
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	2 (7.1)	2	5.0
Toothache									
Yes	1 (1.4)	1	1.0	0			1 (1.4)	1	1.0
No	0			2 (4.3)	2	3.0	0		
Tooth impacted									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Dental cyst									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Gastrointestinal conditions NEC									
Yes	4 (5.5)	4	3.9	9 (5.9)	11	5.3	1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Gastric disorder									
Yes	2 (2.7)	2	1.9	2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		
Gastrointestinal disorder									
Yes	2 (2.7)	2	1.9	4 (2.6)	6	2.9	0		
No	0			0			0		
Food poisoning									
Yes	0			3 (2.0)	3	1.4	0		
No	0			0			0		
Barrett's oesophagus									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions									
Yes	1 (1.4)	1	1.0	9 (5.9)	10	4.8	2 (2.7)	2	2.0
No	0			1 (2.1)	1	1.5	3 (10.7)	3	7.5
Enterocolitis									
Yes	1 (1.4)	1	1.0	4 (2.6)	4	1.9	0		
No	0			0			1 (3.6)	1	2.5
Colitis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Gastritis									
Yes	0			3 (2.0)	3	1.4	1 (1.4)	1	1.0
No	0			0			2 (7.1)	2	5.0
Chronic gastritis									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Colitis ischaemic									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Enteritis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Benign neoplasms gastrointestinal									
Yes	3 (4.1)	3	2.9	4 (2.6)	5	2.4	2 (2.7)	2	2.0
No	0			2 (4.3)	2	3.0	0		
Large intestine polyp									
Yes	2 (2.7)	2	1.9	2 (1.3)	2	1.0	2 (2.7)	2	2.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			2 (4.3)	2	3.0	0		
Gastric polyps									
Yes	0			3 (2.0)	3	1.4	0		
No	0			0			0		
Rectal polyp									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Oral soft tissue conditions									
Yes	0			2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		
Angular cheilitis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Stomatitis									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Diverticular disorders									
Yes	2 (2.7)	2	1.9	0			0		
No	0			1 (2.1)	1	1.5	0		
Diverticulum intestinal									
Yes	2 (2.7)	2	1.9	0			0		
No	0			1 (2.1)	1	1.5	0		
Gastrointestinal haemorrhages NEC									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Anal haemorrhage									
Yes	0			1 (0.7)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Mallory-Weiss syndrome									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Anal and rectal conditions NEC									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			0		
Anal fissure									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			0		
Gastrointestinal ulceration and perforation									
Yes	0			1 (0.7)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		
Erosive duodenitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Gastritis erosive									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Gastrointestinal vascular conditions									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Haemorrhoids									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal stenosis and obstruction									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Intestinal obstruction									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Salivary gland conditions									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Parotid gland enlargement									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Infections and infestations									
Yes	31 (42.5)	44	42.8	60 (39.5)	118	56.5	22 (30.1)	31	30.4
No	11 (40.7)	20	60.0	20 (42.6)	35	52.9	13 (46.4)	22	55.1
Infections - pathogen unspecified									
Yes	28 (38.4)	39	37.9	54 (35.5)	103	49.3	22 (30.1)	30	29.4
No	11 (40.7)	19	57.0	17 (36.2)	29	43.9	12 (42.9)	21	52.6
Nasopharyngitis									
Yes	18 (24.7)	28	27.2	40 (26.3)	65	31.1	12 (16.4)	16	15.7
No	6 (22.2)	8	24.0	13 (27.7)	16	24.2	6 (21.4)	8	20.0
Gastroenteritis									
Yes	4 (5.5)	4	3.9	9 (5.9)	11	5.3	1 (1.4)	1	1.0
No	3 (11.1)	4	12.0	2 (4.3)	2	3.0	0		
Bronchitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	3 (2.0)	6	2.9	0		
No	2 (7.4)	2	6.0	3 (6.4)	3	4.5	0		
Pharyngitis									
Yes	1 (1.4)	1	1.0	1 (0.7)	2	1.0	2 (2.7)	2	2.0
No	2 (7.4)	2	6.0	2 (4.3)	2	3.0	2 (7.1)	3	7.5
Tonsillitis									
Yes	1 (1.4)	1	1.0	0			2 (2.7)	3	2.9
No	0			2 (4.3)	2	3.0	1 (3.6)	1	2.5
Rhinitis									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	1 (3.6)	1	2.5
Acute sinusitis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Hordeolum									
Yes	1 (1.4)	1	1.0	0			1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Pelvic inflammatory disease									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Cystitis									
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	1 (1.4)	2	2.0
No	0			0			0		
Conjunctivitis									
Yes	0			2 (1.3)	3	1.4	0		
No	0			0			2 (7.1)	2	5.0
Diverticulitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Enteritis infectious									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Folliculitis									
Yes	0			1	(0.7)	2 1.0	0		
No	0			0			0		
Gingivitis									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Pyelonephritis									
Yes	1	(1.4)	1 1.0	1	(0.7)	1 0.5	0		
No	0			0			0		
Pyelonephritis acute									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Sinusitis									
Yes	0			1	(0.7)	1 0.5	2	(2.7)	2 2.0
No	1	(3.7)	1 3.0	0			1	(3.6)	1 2.5
Urethritis									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Urinary tract infection									
Yes	1	(1.4)	1 1.0	1	(0.7)	3 1.4	0		
No	0			0			0		
Periodontitis									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Pyoderma									
Yes	0			0			1 (1.4)	2	2.0
No	0			0			0		
Upper respiratory tract infection									
Yes	0			0			0		
No	0			0			2 (7.1)	3	7.5
Vaginal infection									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Viral infectious disorders									
Yes	4 (5.5)	4	3.9	10 (6.6)	11	5.3	0		
No	1 (3.7)	1	3.0	3 (6.4)	3	4.5	1 (3.6)	1	2.5
Influenza									
Yes	1 (1.4)	1	1.0	6 (3.9)	6	2.9	0		
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	1 (3.6)	1	2.5
Gastroenteritis viral									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			1 (2.1)	1	1.5	0		
Herpes zoster									
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	0		
No	0			0			0		
Herpes simplex									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Infectious mononucleosis									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Fungal infectious disorders									
Yes	0			0			0		
No	0			2 (4.3)	2	3.0	0		
Tinea pedis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Vulvovaginal candidiasis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Bacterial infectious disorders									
Yes	1 (1.4)	1	1.0	3 (2.0)	4	1.9	1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Furuncle									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Alpha haemolytic streptococcal infection									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Cellulitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Erysipelas									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Helicobacter infection									
Yes	1 (1.4)	1	1.0	0			1 (1.4)	1	1.0
No	0			0			0		
Nervous system disorders									
Yes	6 (8.2)	7	6.8	22 (14.5)	31	14.8	5 (6.8)	5	4.9
No	2 (7.4)	4	12.0	13 (27.7)	21	31.8	1 (3.6)	1	2.5
Neurological disorders NEC									
Yes	5 (6.8)	5	4.9	16 (10.5)	20	9.6	2 (2.7)	2	2.0
No	1 (3.7)	3	9.0	6 (12.8)	13	19.7	1 (3.6)	1	2.5
Dizziness									
Yes	2 (2.7)	2	1.9	10 (6.6)	12	5.7	0		
No	1 (3.7)	3	9.0	4 (8.5)	7	10.6	0		
Hypoaesthesia									
Yes	2 (2.7)	2	1.9	2 (1.3)	3	1.4	0		
No	0			1 (2.1)	1	1.5	0		
Dysaesthesia									
Yes	0			0			0		
No	0			1 (2.1)	2	3.0	0		
Dysgeusia									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Paraesthesia									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	1 (3.6)	1	2.5
Somnolence									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (2.1)	1	1.5	0		
Dizziness postural									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		
Neuralgia									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Neurological symptom									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Taste disorder									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Intercostal neuralgia									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Sensory loss									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Headaches									
Yes	1 (1.4)	1	1.0	6 (3.9)	7	3.4	3 (4.1)	3	2.9
No	1 (3.7)	1	3.0	4 (8.5)	5	7.6	0		
Headache									
Yes	1 (1.4)	1	1.0	6 (3.9)	7	3.4	3 (4.1)	3	2.9
No	1 (3.7)	1	3.0	4 (8.5)	5	7.6	0		
Spinal cord and nerve root disorders									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (2.1)	1	1.5	0		
Sciatica									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		
Cranial nerve disorders (excl neoplasms)									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Parosmia									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Neuromuscular disorders									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Autonomic nervous system imbalance									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Central nervous system vascular disorders									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Lacunar infarction									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Peripheral neuropathies									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Carpal tunnel syndrome									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Musculoskeletal and connective tissue disorders									
Yes	17 (23.3)	26	25.3	34 (22.4)	40	19.1	17 (23.3)	25	24.5
No	7 (25.9)	8	24.0	9 (19.1)	12	18.1	7 (25.0)	9	22.6
Musculoskeletal and connective tissue disorders NEC									
Yes	6 (8.2)	10	9.7	19 (12.5)	20	9.6	8 (11.0)	10	9.8
No	4 (14.8)	4	12.0	3 (6.4)	3	4.5	5 (17.9)	5	12.5
Back pain									
Yes	5 (6.8)	9	8.7	16 (10.5)	17	8.1	6 (8.2)	8	7.8
No	3 (11.1)	3	9.0	3 (6.4)	3	4.5	3 (10.7)	3	7.5
Musculoskeletal discomfort									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Neck pain									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Pain in extremity									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Musculoskeletal pain									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Musculoskeletal stiffness									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Joint disorders									
Yes	11 (15.1)	13	12.6	10 (6.6)	10	4.8	9 (12.3)	13	12.8
No	4 (14.8)	4	12.0	3 (6.4)	3	4.5	2 (7.1)	3	7.5
Periarthritis									
Yes	2 (2.7)	2	1.9	2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	0			2 (4.3)	2	3.0	0		
Arthralgia									
Yes	6 (8.2)	7	6.8	4 (2.6)	4	1.9	5 (6.8)	7	6.9
No	3 (11.1)	3	9.0	1 (2.1)	1	1.5	1 (3.6)	2	5.0
Osteoarthritis									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	2 (2.7)	2	2.0
No	1 (3.7)	1	3.0	0			0		
Rotator cuff syndrome									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Spinal osteoarthritis									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Arthritis									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Articular calcification									
Yes	0			0			1 (1.4)	2	2.0
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Muscle disorders									
Yes	1 (1.4)	1	1.0	6 (3.9)	6	2.9	0		
No	0			3 (6.4)	3	4.5	1 (3.6)	1	2.5
Myalgia									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			2 (4.3)	2	3.0	1 (3.6)	1	2.5
Muscle spasms									
Yes	0			2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		
Fibromyalgia									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Rhabdomyolysis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Tendon, ligament and cartilage disorders									
Yes	1 (1.4)	1	1.0	1 (0.7)	2	1.0	0		
No	0			2 (4.3)	2	3.0	0		
Tendonitis									
Yes	1 (1.4)	1	1.0	0			0		
No	0			2 (4.3)	2	3.0	0		
Trigger finger									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		
Synovial and bursal disorders									
Yes	0			0			1 (1.4)	1	1.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (2.1)	1	1.5	0		
Bursitis									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Synovitis									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		
Intervertebral disc protrusion									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Spinal stenosis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Injury, poisoning and procedural complications									
Yes	11 (15.1)	15	14.6	19 (12.5)	20	9.6	7 (9.6)	9	8.8
No	4 (14.8)	4	12.0	6 (12.8)	6	9.1	5 (17.9)	5	12.5
Injuries NEC									
Yes	4 (5.5)	8	7.8	13 (8.6)	14	6.7	6 (8.2)	7	6.9
No	2 (7.4)	2	6.0	4 (8.5)	4	6.0	3 (10.7)	3	7.5
Contusion									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	0		
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	0		
Limb injury									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Subcutaneous haematoma									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Tooth fracture									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Arthropod sting									
Yes	0			3 (2.0)	3	1.4	0		
No	0			0			0		
Ligament sprain									
Yes	3 (4.1)	4	3.9	3 (2.0)	3	1.4	1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Tendon rupture									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		
Arthropod bite									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Epicondylitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Post-traumatic neck syndrome									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.7)	1	0.5	2 (2.7)	2	2.0
No	0			0			0		
Limb crushing injury									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Muscle contusion									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Muscle strain									
Yes	1 (1.4)	2	1.9	0			0		
No	0			0			0		
Road traffic accident									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Skin laceration									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Subdural haematoma									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Bone and joint injuries									
Yes	5 (6.8)	5	4.9	3 (2.0)	3	1.4	1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Ankle fracture									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Meniscus injury									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Radius fracture									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Rib fracture									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			0		
Fracture									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Joint injury									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Medication errors and other product use errors and issues									
Yes	0			1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	0		
Accidental overdose									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Product administration error									
Yes	0			1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			0		
Injuries by physical agents									
Yes	2 (2.7)	2	1.9	2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			2 (7.1)	2	5.0

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Heat stroke									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Thermal burn									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Heat illness									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			2 (7.1)	2	5.0
Skin and subcutaneous tissue disorders									
Yes	11 (15.1)	19	18.5	18 (11.8)	23	11.0	4 (5.5)	6	5.9
No	2 (7.4)	3	9.0	6 (12.8)	7	10.6	7 (25.0)	8	20.0
Epidermal and dermal conditions									
Yes	9 (12.3)	12	11.7	13 (8.6)	14	6.7	3 (4.1)	4	3.9
No	1 (3.7)	1	3.0	4 (8.5)	5	7.6	5 (17.9)	6	15.0
Eczema									
Yes	3 (4.1)	3	2.9	3 (2.0)	3	1.4	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	1 (3.6)	1	2.5
Pruritus									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	2 (7.1)	3	7.5
Dermatitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			1 (2.1)	2	3.0	0		
Dyshidrotic eczema									
Yes	0			0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (2.1)	1	1.5	0		
Eczema asteatotic									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			0		
Dermatitis atopic									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		
Dermatitis contact									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			2 (7.1)	2	5.0
Erythema									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Rash									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Stasis dermatitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Drug eruption									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Dry skin									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Pain of skin									
Yes	1 (1.4)	1	1.0	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Rash pruritic									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Seborrhoeic dermatitis									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Xanthelasma									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Skin appendage conditions									
Yes	4 (5.5)	4	3.9	6 (3.9)	6	2.9	1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	1 (3.6)	1	2.5
Alopecia									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	0			1 (2.1)	1	1.5	0		
Alopecia areata									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Acne									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Ingrowing nail									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Miliaria									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (3.6)	1	2.5
Angioedema and urticaria									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	1 (3.7)	2	6.0	1 (2.1)	1	1.5	1 (3.6)	1	2.5
Urticaria									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	1 (3.7)	2	6.0	1 (2.1)	1	1.5	1 (3.6)	1	2.5
Cornification and dystrophic skin disorders									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			0		
Hyperkeratosis									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Xeroderma									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Yes	7 (9.6)	10	9.7	19 (12.5)	22	10.5	9 (12.3)	14	13.7
No	3 (11.1)	3	9.0	5 (10.6)	5	7.6	4 (14.3)	5	12.5
Respiratory tract signs and symptoms									
Yes	5 (6.8)	6	5.8	13 (8.6)	15	7.2	9 (12.3)	13	12.8
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	2 (7.1)	2	5.0
Upper respiratory tract inflammation									
Yes	5 (6.8)	6	5.8	9 (5.9)	11	5.3	8 (11.0)	12	11.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			2 (4.3)	2	3.0	1 (3.6)	1	2.5
Oropharyngeal pain									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Hiccups									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Rhinorrhoea									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Upper respiratory tract disorders (excl infections)									
Yes	2 (2.7)	2	1.9	4 (2.6)	4	1.9	0		
No	0			3 (6.4)	3	4.5	1 (3.6)	2	5.0
Rhinitis allergic									
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	0		
No	0			3 (6.4)	3	4.5	1 (3.6)	2	5.0
Epistaxis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Vasomotor rhinitis									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Respiratory disorders NEC									
Yes	0			2 (1.3)	2	1.0	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Cough									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Dyspnoea									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Bronchial disorders (excl neoplasms)									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
Asthma									
Yes	0			1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			0		
Cough variant asthma									
Yes	2 (2.7)	2	1.9	0			1 (1.4)	1	1.0
No	0			0			0		
Metabolism and nutrition disorders									
Yes	5 (6.8)	5	4.9	18 (11.8)	19	9.1	7 (9.6)	10	9.8
No	1 (3.7)	1	3.0	5 (10.6)	5	7.6	1 (3.6)	1	2.5
Appetite and general nutritional disorders									
Yes	4 (5.5)	4	3.9	11 (7.2)	11	5.3	0		
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	0		
Decreased appetite									
Yes	4 (5.5)	4	3.9	11 (7.2)	11	5.3	0		
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	0		
Purine and pyrimidine metabolism disorders									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	3 (4.1)	4	3.9
No	0			2 (4.3)	2	3.0	1 (3.6)	1	2.5
Gout									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	2	2.0
No	0			1 (2.1)	1	1.5	0		
Hyperuricaemia									
Yes	0			1 (0.7)	1	0.5	2 (2.7)	2	2.0
No	0			1 (2.1)	1	1.5	1 (3.6)	1	2.5
Glucose metabolism disorders (incl diabetes mellitus)									
Yes	0			1 (0.7)	2	1.0	3 (4.1)	4	3.9
No	0			1 (2.1)	1	1.5	0		
Diabetes mellitus									
Yes	0			0			1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Type 2 diabetes mellitus									
Yes	0			1 (0.7)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		
Glucose tolerance impaired									
Yes	0			0			1 (1.4)	2	2.0
No	0			0			0		
Lipid metabolism disorders									
Yes	0			2 (1.3)	2	1.0	2 (2.7)	2	2.0
No	0			0			0		
Dyslipidaemia									
Yes	0			2 (1.3)	2	1.0	2 (2.7)	2	2.0
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Electrolyte and fluid balance conditions									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Dehydration									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Metabolism disorders NEC									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Hypercreatininaemia									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
General disorders and administration site conditions									
Yes	1 (1.4)	1	1.0	11 (7.2)	26	12.4	2 (2.7)	2	2.0
No	2 (7.4)	4	12.0	5 (10.6)	9	13.6	0		
General system disorders NEC									
Yes	1 (1.4)	1	1.0	6 (3.9)	9	4.3	1 (1.4)	1	1.0
No	1 (3.7)	3	9.0	5 (10.6)	9	13.6	0		
Malaise									
Yes	1 (1.4)	1	1.0	3 (2.0)	4	1.9	0		
No	0			2 (4.3)	4	6.0	0		
Fatigue									
Yes	0			2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Feeling abnormal									
Yes	0			1	(0.7)	1 0.5	0		
No	0			1	(2.1)	1 1.5	0		
Influenza like illness									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Oedema peripheral									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Pain									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Non-cardiac chest pain									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Thirst									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Hangover									
Yes	0			0			0		
No	1	(3.7)	3 9.0	0			0		
Hunger									
Yes	0			0			1	(1.4)	1 1.0
No	0			0			0		
Administration site reactions									
Yes	0			4	(2.6)	15 7.2	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Injection site erythema									
Yes	0			2 (1.3)	13	6.2	0		
No	0			0			0		
Injection site dermatitis									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Injection site discomfort									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Body temperature conditions									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
Pyrexia									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
Investigations									
Yes	10 (13.7)	11	10.7	11 (7.2)	13	6.2	5 (6.8)	6	5.9
No	3 (11.1)	5	15.0	5 (10.6)	7	10.6	4 (14.3)	5	12.5
Enzyme investigations NEC									
Yes	3 (4.1)	3	2.9	4 (2.6)	5	2.4	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	1 (3.6)	1	2.5
Blood creatine phosphokinase increased									
Yes	3 (4.1)	3	2.9	4 (2.6)	5	2.4	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	2 (4.3)	2	3.0	1 (3.6)	1	2.5
Gastrointestinal investigations									
Yes	4 (5.5)	4	3.9	2 (1.3)	2	1.0	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	1 (3.7)	1	3.0	2 (4.3)	3	4.5	0		
Lipase increased									
Yes	3 (4.1)	3	2.9	2 (1.3)	2	1.0	0		
No	0			2 (4.3)	2	3.0	0		
Amylase increased									
Yes	0			0			0		
No	1 (3.7)	1	3.0	1 (2.1)	1	1.5	0		
Occult blood positive									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Hepatobiliary investigations									
Yes	0			1 (0.7)	1	0.5	3 (4.1)	3	2.9
No	0			1 (2.1)	1	1.5	2 (7.1)	2	5.0
Aspartate aminotransferase increased									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Liver function test increased									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Alanine aminotransferase increased									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Blood bilirubin increased									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Endocrine investigations (incl sex hormones)									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Yes	0				0				0			
No	0				1	(2.1)	1	1.5	0			
Blood thyroid stimulating hormone decreased												
Yes	0				0				0			
No	0				1	(2.1)	1	1.5	0			
Cardiac and vascular investigations (excl enzyme tests)												
Yes	2	(2.7)	2	1.9	3	(2.0)	3	1.4	0			
No	0				0				0			
Blood pressure decreased												
Yes	0				3	(2.0)	3	1.4	0			
No	0				0				0			
Electrocardiogram QRS complex prolonged												
Yes	1	(1.4)	1	1.0	0				0			
No	0				0				0			
Electrocardiogram QT prolonged												
Yes	1	(1.4)	1	1.0	0				0			
No	0				0				0			
Haematology investigations (incl blood groups)												
Yes	0				1	(0.7)	1	0.5	0			
No	1	(3.7)	2	6.0	0				0			
Haemoglobin decreased												
Yes	0				1	(0.7)	1	0.5	0			
No	0				0				0			

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lymphocyte count decreased									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
White blood cell count increased									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Physical examination and organ system status topics									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Weight decreased									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Lipid analyses									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Blood triglycerides increased									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Metabolic, nutritional and blood gas investigations									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			1 (3.6)	1	2.5
Blood uric acid increased									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Glycosylated haemoglobin increased									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Protein and chemistry analyses NEC									
Yes	0			0			1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
C-reactive protein increased									
Yes	0			0			1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
Water, electrolyte and mineral investigations									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Blood potassium increased									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Eye disorders									
Yes	4 (5.5)	5	4.9	13 (8.6)	15	7.2	1 (1.4)	1	1.0
No	2 (7.4)	2	6.0	4 (8.5)	4	6.0	6 (21.4)	7	17.5
Retina, choroid and vitreous haemorrhages and vascular disorders									
Yes	2 (2.7)	3	2.9	3 (2.0)	3	1.4	0		
No	0			2 (4.3)	2	3.0	2 (7.1)	2	5.0
Diabetic retinopathy									
Yes	1 (1.4)	2	1.9	1 (0.7)	1	0.5	0		
No	0			2 (4.3)	2	3.0	2 (7.1)	2	5.0
Retinal exudates									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Retinal haemorrhage									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Retinopathy									
Yes	1	(1.4)	1 1.0	0			0		
No	0			0			0		
Vision disorders									
Yes	0			3	(2.0)	3 1.4	0		
No	0			1	(2.1)	1 1.5	0		
Amblyopia									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Optic nerve disorder									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Presbyopia									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Visual acuity reduced									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Glaucoma and ocular hypertension									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	1	(3.6)	1 2.5
Glaucoma									

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Open angle glaucoma									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Anterior eye structural change, deposit and degeneration									
Yes	0			3 (2.0)	3	1.4	0		
No	0			0			1 (3.6)	1	2.5
Cataract									
Yes	0			3 (2.0)	3	1.4	0		
No	0			0			1 (3.6)	1	2.5
Ocular infections, irritations and inflammations									
Yes	0			2 (1.3)	2	1.0	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Conjunctivitis allergic									
Yes	0			1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Ocular hyperaemia									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Eye disorders NEC									
Yes	1 (1.4)	1	1.0	1 (0.7)	2	1.0	0		
No	0			0			1 (3.6)	1	2.5
Lacrimal disorder									
Yes	0			1 (0.7)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Lacrimation increased									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Dry eye									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			1 (3.6)	1	2.5
Ocular haemorrhages and vascular disorders NEC									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Optic disc haemorrhage									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Conjunctival haemorrhage									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Ocular structural change, deposit and degeneration NEC									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		
Retinal tear									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		
Macular fibrosis									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Rhegmatogenous retinal detachment									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Vascular disorders									
Yes	2 (2.7)	2	1.9	10 (6.6)	10	4.8	3 (4.1)	3	2.9
No	0			1 (2.1)	1	1.5	1 (3.6)	1	2.5
Decreased and nonspecific blood pressure disorders and shock									
Yes	0			4 (2.6)	4	1.9	0		
No	0			1 (2.1)	1	1.5	0		
Orthostatic hypotension									
Yes	0			2 (1.3)	2	1.0	0		
No	0			1 (2.1)	1	1.5	0		
Hypotension									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Vascular hypertensive disorders									
Yes	1 (1.4)	1	1.0	4 (2.6)	4	1.9	2 (2.7)	2	2.0
No	0			0			1 (3.6)	1	2.5
Hypertension									
Yes	1 (1.4)	1	1.0	4 (2.6)	4	1.9	2 (2.7)	2	2.0
No	0			0			1 (3.6)	1	2.5
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Arteriosclerosis									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	0			0			0		
Embolism and thrombosis									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Venous thrombosis limb									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Reproductive system and breast disorders									
Yes	2 (2.7)	2	1.9	8 (5.3)	9	4.3	0		
No	1 (3.7)	2	6.0	1 (2.1)	1	1.5	0		
Menstrual cycle and uterine bleeding disorders									
Yes	0			3 (2.0)	3	1.4	0		
No	0			1 (2.1)	1	1.5	0		
Menstrual disorder									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Dysmenorrhoea									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Menstruation irregular									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Prostatic disorders (excl infections and inflammations)									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			0		
Benign prostatic hyperplasia									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			0		
Breast disorders									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Breast calcifications									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Male reproductive tract infections and inflammations									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		
Prostatitis									
Yes	0			1 (0.7)	2	1.0	0		
No	0			0			0		
Menopause related conditions									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Menopausal symptoms									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Uterine, pelvic and broad ligament disorders									
Yes	1 (1.4)	1	1.0	0			0		
No	1 (3.7)	2	6.0	0			0		
Endometrial hyperplasia									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Endometriosis									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Uterine haemorrhage									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Psychiatric disorders									
Yes	2 (2.7)	2	1.9	4 (2.6)	4	1.9	1 (1.4)	1	1.0
No	2 (7.4)	2	6.0	2 (4.3)	2	3.0	0		
Sleep disorders and disturbances									
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	0		
No	2 (7.4)	2	6.0	1 (2.1)	1	1.5	0		
Insomnia									
Yes	1 (1.4)	1	1.0	3 (2.0)	3	1.4	0		
No	2 (7.4)	2	6.0	1 (2.1)	1	1.5	0		
Depressed mood disorders and disturbances									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Depression									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Mood disorders and disturbances NEC									
Yes	0			1 (0.7)	1	0.5	1 (1.4)	1	1.0
No	0			0			0		
Emotional disorder									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Listless									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Adjustment disorders (incl subtypes)									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Adjustment disorder									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Renal and urinary disorders									
Yes	5 (6.8)	6	5.8	4 (2.6)	4	1.9	3 (4.1)	5	4.9
No	0			1 (2.1)	1	1.5	2 (7.1)	2	5.0
Urolithiases									
Yes	3 (4.1)	3	2.9	1 (0.7)	1	0.5	3 (4.1)	5	4.9
No	0			1 (2.1)	1	1.5	0		
Ureterolithiasis									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	2 (2.7)	4	3.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			1 (2.1)	1	1.5	0		
Calculus urinary									
Yes	2 (2.7)	2	1.9	0			1 (1.4)	1	1.0
No	0			0			0		
Renal disorders (excl nephropathies)									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			1 (3.6)	1	2.5
Azotaemia									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Renal cyst									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			1 (3.6)	1	2.5
Urinary tract signs and symptoms									
Yes	1 (1.4)	2	1.9	1 (0.7)	1	0.5	0		
No	0			0			0		
Hyperuricosuria									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Nocturia									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Proteinuria									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Nephropathies									
Yes	1 (1.4)	1	1.0	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			1 (3.6)	1	2.5
Diabetic nephropathy									
Yes	0			0			0		
No	0			0			1 (3.6)	1	2.5
Nephropathy toxic									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Cardiac disorders									
Yes	2 (2.7)	2	1.9	3 (2.0)	3	1.4	3 (4.1)	3	2.9
No	0			1 (2.1)	1	1.5	0		
Cardiac disorders, signs and symptoms NEC									
Yes	1 (1.4)	1	1.0	0			1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Palpitations									
Yes	1 (1.4)	1	1.0	0			1 (1.4)	1	1.0
No	0			1 (2.1)	1	1.5	0		
Cardiac arrhythmias									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	2 (2.7)	2	2.0
No	0			0			0		
Tachycardia									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Ventricular extrasystoles									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Arrhythmia									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Atrial fibrillation									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Coronary artery disorders									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Acute myocardial infarction									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Ear and labyrinth disorders									
Yes	2 (2.7)	2	1.9	2 (1.3)	2	1.0	0		
No	2 (7.4)	2	6.0	1 (2.1)	1	1.5	1 (3.6)	1	2.5
Hearing disorders									
Yes	0			1 (0.7)	1	0.5	0		
No	0			1 (2.1)	1	1.5	0		
Deafness									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Deafness neurosensory									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Inner ear and VIIIth cranial nerve disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	2 (7.4)	2	6.0	0			1 (3.6)	1	2.5
Vertigo									
Yes	2 (2.7)	2	1.9	1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Tinnitus									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Hepatobiliary disorders									
Yes	0			5 (3.3)	5	2.4	1 (1.4)	1	1.0
No	2 (7.4)	2	6.0	0			0		
Gallbladder disorders									
Yes	0			3 (2.0)	3	1.4	0		
No	1 (3.7)	1	3.0	0			0		
Cholelithiasis									
Yes	0			2 (1.3)	2	1.0	0		
No	0			0			0		
Gallbladder polyp									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Hyperplastic cholecystopathy									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Hepatic and hepatobiliary disorders									
Yes	0			2 (1.3)	2	1.0	1 (1.4)	1	1.0
No	1 (3.7)	1	3.0	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hepatic cyst									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Hepatic function abnormal									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Alcoholic liver disease									
Yes	0			0			1	(1.4)	1 1.0
No	0			0			0		
Hepatic steatosis									
Yes	0			0			0		
No	1	(3.7)	1 3.0	0			0		
Congenital, familial and genetic disorders									
Yes	0			1	(0.7)	1 0.5	0		
No	0			1	(2.1)	1 1.5	0		
Skin and subcutaneous tissue disorders congenital									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Birth mark									
Yes	0			0			0		
No	0			1	(2.1)	1 1.5	0		
Gastrointestinal tract disorders congenital									
Yes	0			1	(0.7)	1 0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
No	0			0			0		
Diverticulitis Meckel's									
Yes	0			1 (0.7)	1	0.5	0		
No	0			0			0		
Endocrine disorders									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Thyroid gland disorders									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Hyperthyroidism									
Yes	0			0			0		
No	0			1 (2.1)	1	1.5	0		
Blood and lymphatic system disorders									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Anaemias nonhaemolytic and marrow depression									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			1 (3.6)	1	2.5
Iron deficiency anaemia									
Yes	1 (1.4)	1	1.0	2 (1.3)	2	1.0	0		
No	0			0			0		
Anaemia									
Yes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
No	0			0			1	(3.6)	1 2.5
Spleen, lymphatic and reticuloendothelial system disorders									
Yes	0			0			0		
No	1	(3.7)	1 3.0	0			0		
Lymphadenitis									
Yes	0			0			0		
No	1	(3.7)	1 3.0	0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Yes	1	(1.4)	1 1.0	2	(1.3)	2 1.0	1	(1.4)	1 1.0
No	1	(3.7)	1 3.0	0			0		
Gastrointestinal neoplasms benign									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Intraductal papillary mucinous neoplasm									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Reproductive neoplasms female benign									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Uterine leiomyoma									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Hepatobiliary neoplasms malignant and unspecified									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Bile duct adenocarcinoma									
Yes	1 (1.4)	1	1.0	0			0		
No	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Clear cell renal cell carcinoma									
Yes	0			0			0		
No	1 (3.7)	1	3.0	0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Lung neoplasm malignant									
Yes	0			0			1 (1.4)	1	1.0
No	0			0			0		
Immune system disorders									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Allergic conditions									
Yes	1 (1.4)	1	1.0	1 (0.7)	1	0.5	0		
No	1 (3.7)	1	3.0	0			1 (3.6)	1	2.5
Seasonal allergy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by hypertension at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Yes	1	(1.4)	1 1.0	1	(0.7)	1 0.5	0		
No	0			0			1	(3.6)	1 2.5
Food allergy									
Yes	0			0			0		
No	1	(3.7)	1 3.0	0			0		
Surgical and medical procedures									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Gastrointestinal therapeutic procedures									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		
Large intestinal polypectomy									
Yes	0			1	(0.7)	1 0.5	0		
No	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

43 Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
Normo-glycaemia	713	931.6			392	495.5		
Pre-diabetes	593	774.5			263	334.1		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Events								
Normo-glycaemia	640	(89.8)	5230	561.4	330	(84.2)	1861	375.6
Pre-diabetes	531	(89.5)	4428	571.8	236	(89.7)	1441	431.3
Serious								
Yes								
Normo-glycaemia	62	(8.7)	81	8.7	18	(4.6)	19	3.8
Pre-diabetes	66	(11.1)	83	10.7	24	(9.1)	34	10.2
No								
Normo-glycaemia	638	(89.5)	5149	552.7	328	(83.7)	1842	371.8
Pre-diabetes	531	(89.5)	4345	561.0	232	(88.2)	1407	421.1
Severity								
Severe								
Normo-glycaemia	75	(10.5)	123	13.2	18	(4.6)	24	4.8
Pre-diabetes	68	(11.5)	119	15.4	26	(9.9)	44	13.2
Moderate								
Normo-glycaemia	400	(56.1)	1514	162.5	184	(46.9)	487	98.3
Pre-diabetes	323	(54.5)	1098	141.8	127	(48.3)	376	112.5
Mild								
Normo-glycaemia	590	(82.7)	3593	385.7	294	(75.0)	1350	272.5
Pre-diabetes	489	(82.5)	3211	414.6	213	(81.0)	1021	305.6

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Relationship to trial product								
Missing								
Normo-glycaemia	12	(1.7)	18	1.9	4	(1.0)	5	1.0
Pre-diabetes	12	(2.0)	12	1.5	3	(1.1)	3	0.9
Probable								
Normo-glycaemia	329	(46.1)	1247	133.9	95	(24.2)	202	40.8
Pre-diabetes	242	(40.8)	901	116.3	52	(19.8)	128	38.3
Possible								
Normo-glycaemia	401	(56.2)	1373	147.4	126	(32.1)	300	60.5
Pre-diabetes	325	(54.8)	1327	171.3	97	(36.9)	255	76.3
Unlikely								
Normo-glycaemia	566	(79.4)	2592	278.2	313	(79.8)	1354	273.3
Pre-diabetes	466	(78.6)	2188	282.5	223	(84.8)	1055	315.8
Outcome								
Fatal								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Recovered								
Normo-glycaemia	627	(87.9)	4627	496.7	314	(80.1)	1532	309.2
Pre-diabetes	513	(86.5)	3812	492.2	231	(87.8)	1178	352.6
Recovering								
Normo-glycaemia	29	(4.1)	46	4.9	12	(3.1)	20	4.0
Pre-diabetes	30	(5.1)	45	5.8	13	(4.9)	17	5.1
Recovered With Sequelae								
Normo-glycaemia	4	(0.6)	7	0.8	3	(0.8)	3	0.6
Pre-diabetes	7	(1.2)	12	1.5	1	(0.4)	2	0.6
Not Recovered								
Normo-glycaemia	276	(38.7)	550	59.0	149	(38.0)	305	61.6

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Outcome								
Not Recovered								
Pre-diabetes	237	(40.0)	556	71.8	116	(44.1)	243	72.7
Unknown								
Normo-glycaemia	0				0			
Pre-diabetes	2	(0.3)	3	0.4	1	(0.4)	1	0.3
Leading to								
Permanent treatment discontinuation								
Normo-glycaemia	48	(6.7)	61	6.5	10	(2.6)	13	2.6
Pre-diabetes	44	(7.4)	62	8.0	10	(3.8)	10	3.0
Temporary interruption of trial product								
Normo-glycaemia	77	(10.8)	165	17.7	11	(2.8)	16	3.2
Pre-diabetes	49	(8.3)	100	12.9	15	(5.7)	28	8.4
Dose reduction of trial product								
Normo-glycaemia	87	(12.2)	155	16.6	2	(0.5)	3	0.6
Pre-diabetes	37	(6.2)	70	9.0	2	(0.8)	6	1.8

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

44 Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
Normo-glycaemia	713	931.6			392	495.5		
Pre-diabetes	593	774.5			263	334.1		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Adverse events								
Normo-glycaemia	640	(89.8)	5230	561.4	330	(84.2)	1861	375.6
Pre-diabetes	531	(89.5)	4428	571.8	236	(89.7)	1441	431.3
Gastrointestinal disorders								
Normo-glycaemia	534	(74.9)	2363	253.6	180	(45.9)	399	80.5
Pre-diabetes	435	(73.4)	1946	251.3	134	(51.0)	340	101.8
Gastrointestinal signs and symptoms								
Normo-glycaemia	462	(64.8)	1548	166.2	115	(29.3)	215	43.4
Pre-diabetes	362	(61.0)	1166	150.6	86	(32.7)	180	53.9
Nausea								
Normo-glycaemia	333	(46.7)	620	66.5	67	(17.1)	77	15.5
Pre-diabetes	244	(41.1)	448	57.8	47	(17.9)	69	20.7
Vomiting								
Normo-glycaemia	195	(27.3)	375	40.3	24	(6.1)	29	5.9
Pre-diabetes	129	(21.8)	261	33.7	19	(7.2)	23	6.9
Dyspepsia								
Normo-glycaemia	77	(10.8)	101	10.8	14	(3.6)	19	3.8
Pre-diabetes	58	(9.8)	78	10.1	9	(3.4)	11	3.3
Abdominal pain								
Normo-glycaemia	85	(11.9)	111	11.9	20	(5.1)	23	4.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	45 (7.6)	64	8.3	16 (6.1)	18	5.4
Abdominal pain upper						
Normo-glycaemia	80 (11.2)	113	12.1	23 (5.9)	25	5.0
Pre-diabetes	45 (7.6)	63	8.1	12 (4.6)	12	3.6
Eructation						
Normo-glycaemia	68 (9.5)	83	8.9	1 (0.3)	1	0.2
Pre-diabetes	44 (7.4)	56	7.2	2 (0.8)	2	0.6
Abdominal distension						
Normo-glycaemia	45 (6.3)	53	5.7	14 (3.6)	20	4.0
Pre-diabetes	51 (8.6)	82	10.6	17 (6.5)	22	6.6
Flatulence						
Normo-glycaemia	27 (3.8)	33	3.5	10 (2.6)	10	2.0
Pre-diabetes	38 (6.4)	51	6.6	11 (4.2)	12	3.6
Abdominal discomfort						
Normo-glycaemia	24 (3.4)	37	4.0	4 (1.0)	4	0.8
Pre-diabetes	32 (5.4)	42	5.4	5 (1.9)	5	1.5
Abdominal pain lower						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	8 (1.3)	8	1.0	2 (0.8)	2	0.6
Faeces soft						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	3	0.4	3 (1.1)	3	0.9
Regurgitation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	3	0.4	0		
Epigastric discomfort						
Normo-glycaemia	2 (0.3)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Gastrointestinal pain						
Normo-glycaemia	2 (0.3)	3	0.3	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Faeces discoloured						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Gastrointestinal sounds abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Retching						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Breath odour						
Normo-glycaemia	2 (0.3)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Dysphagia						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Abnormal faeces						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oesophageal pain						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Abdominal tenderness						
Normo-glycaemia	1 (0.1)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Aerophagia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Faeces hard						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastrointestinal motility and defaecation conditions						
Normo-glycaemia	335 (47.0)	668	71.7	88 (22.4)	129	26.0
Pre-diabetes	291 (49.1)	603	77.9	78 (29.7)	110	32.9
Diarrhoea						
Normo-glycaemia	214 (30.0)	408	43.8	55 (14.0)	76	15.3
Pre-diabetes	198 (33.4)	358	46.2	49 (18.6)	62	18.6
Constipation						
Normo-glycaemia	167 (23.4)	203	21.8	35 (8.9)	38	7.7
Pre-diabetes	139 (23.4)	187	24.1	27 (10.3)	35	10.5
Gastrooesophageal reflux disease						
Normo-glycaemia	40 (5.6)	44	4.7	10 (2.6)	11	2.2
Pre-diabetes	42 (7.1)	48	6.2	10 (3.8)	10	3.0
Irritable bowel syndrome						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	2 (0.3)	3	0.4	1 (0.4)	2	0.6
Frequent bowel movements						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Impaired gastric emptying						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Dyschezia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Change of bowel habit						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oesophageal achalasia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Bowel movement irregularity						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Defaecation urgency						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Gastrointestinal hypermotility						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastrointestinal motility disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Infrequent bowel movements						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions						
Normo-glycaemia	25 (3.5)	32	3.4	8 (2.0)	9	1.8
Pre-diabetes	46 (7.8)	62	8.0	4 (1.5)	4	1.2
Gastritis						
Normo-glycaemia	16 (2.2)	22	2.4	5 (1.3)	6	1.2
Pre-diabetes	34 (5.7)	45	5.8	1 (0.4)	1	0.3
Colitis						
Normo-glycaemia	4 (0.6)	5	0.5	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	4	0.5	0		
Reflux gastritis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Chronic gastritis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Duodenitis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Enteritis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Gastrointestinal inflammation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oesophagitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Crohn's disease						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Eosinophilic oesophagitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Colitis ischaemic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastroenteritis eosinophilic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Epiploic appendagitis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Inflammatory bowel disease						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Gastrointestinal conditions NEC						
Normo-glycaemia	23 (3.2)	34	3.6	9 (2.3)	10	2.0
Pre-diabetes	25 (4.2)	33	4.3	3 (1.1)	6	1.8
Hyperchlorhydria						
Normo-glycaemia	5 (0.7)	15	1.6	1 (0.3)	2	0.4
Pre-diabetes	15 (2.5)	22	2.8	2 (0.8)	3	0.9
Food poisoning						
Normo-glycaemia	13 (1.8)	13	1.4	3 (0.8)	3	0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	3	0.9
Gastrointestinal disorder						
Normo-glycaemia	3 (0.4)	4	0.4	4 (1.0)	4	0.8
Pre-diabetes	2 (0.3)	3	0.4	0		
Anal fistula						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Barrett's oesophagus						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gastric mucosal hypertrophy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Functional gastrointestinal disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Dental and gingival conditions						
Normo-glycaemia	12 (1.7)	14	1.5	14 (3.6)	16	3.2
Pre-diabetes	15 (2.5)	18	2.3	15 (5.7)	16	4.8
Toothache						
Normo-glycaemia	6 (0.8)	7	0.8	9 (2.3)	9	1.8
Pre-diabetes	11 (1.9)	13	1.7	8 (3.0)	9	2.7
Dental caries						
Normo-glycaemia	2 (0.3)	3	0.3	5 (1.3)	5	1.0
Pre-diabetes	2 (0.3)	2	0.3	5 (1.9)	5	1.5
Gingival disorder						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Periodontal disease						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tooth impacted						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gingival bleeding						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gingival pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Noninfective gingivitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Tooth loss						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Dental necrosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Dental pulp disorder						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Tooth disorder						
Normo-glycaemia	0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Gastrointestinal vascular conditions						
Normo-glycaemia	19 (2.7)	20	2.1	3 (0.8)	3	0.6
Pre-diabetes	9 (1.5)	10	1.3	2 (0.8)	2	0.6
Haemorrhoids						
Normo-glycaemia	17 (2.4)	17	1.8	2 (0.5)	2	0.4
Pre-diabetes	9 (1.5)	10	1.3	1 (0.4)	1	0.3
Haemorrhoidal haemorrhage						
Normo-glycaemia	1 (0.1)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Haemorrhoids thrombosed						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Salivary gland conditions						
Normo-glycaemia	18 (2.5)	18	1.9	5 (1.3)	5	1.0
Pre-diabetes	9 (1.5)	9	1.2	3 (1.1)	4	1.2
Dry mouth						
Normo-glycaemia	17 (2.4)	17	1.8	5 (1.3)	5	1.0
Pre-diabetes	8 (1.3)	8	1.0	2 (0.8)	3	0.9
Salivary gland cyst						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Salivary gland calculus						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Salivary gland enlargement						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Gastrointestinal haemorrhages NEC						
Normo-glycaemia	7 (1.0)	7	0.8	1 (0.3)	1	0.2
Pre-diabetes	8 (1.3)	9	1.2	5 (1.9)	6	1.8
Haematochezia						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	3	0.9
Rectal haemorrhage						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Haematemesis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Lower gastrointestinal haemorrhage						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Melaena						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Upper gastrointestinal haemorrhage						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Benign neoplasms gastrointestinal						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	8 (1.3)	8	1.0	2 (0.8)	2	0.6
Large intestine polyp						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	8 (1.3)	8	1.0	1 (0.4)	1	0.3
Gastric polyps						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Abdominal hernias and other abdominal wall conditions						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	7	0.9	2 (0.8)	2	0.6
Hiatus hernia						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	4 (0.7)	5	0.6	1 (0.4)	1	0.3
Abdominal hernia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Umbilical hernia						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Oral soft tissue conditions						
Normo-glycaemia	5 (0.7)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	4 (1.5)	4	1.2
Lip swelling						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Lip disorder						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Odynophagia						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Paraesthesia oral						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Aphthous ulcer						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Cheilitis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Mouth ulceration						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Stomatitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Oral mucosal eruption						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Diverticular disorders						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	5	0.6	2 (0.8)	2	0.6
Diverticulum						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	5	0.6	2 (0.8)	2	0.6
Anal and rectal conditions NEC						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	4 (0.7)	6	0.8	0		
Anal fissure						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Proctalgia						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	3	0.4	0		
Anorectal discomfort						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Rectal fissure						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Anal pruritus						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastrointestinal ulceration and perforation						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	0		
Duodenal ulcer						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gastric ulcer						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Large intestine perforation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Peptic ulcer						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oesophageal ulcer						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastrointestinal stenosis and obstruction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Ileus						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Oesophageal stenosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Volvulus						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Intestinal obstruction						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Exocrine pancreas conditions						
Normo-glycaemia	2 (0.3)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Pre-diabetes	0				0			
Pancreatitis acute								
Normo-glycaemia	2	(0.3)	2	0.2	0			
Pre-diabetes	0				0			
Peritoneal and retroperitoneal conditions								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Pneumoperitoneum								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Malabsorption conditions								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Coeliac disease								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Tongue conditions								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Glossodynia								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Infections and infestations								
Normo-glycaemia	392	(55.0)	907	97.4	217	(55.4)	482	97.3
Pre-diabetes	322	(54.3)	708	91.4	155	(58.9)	320	95.8

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Infections - pathogen unspecified						
Normo-glycaemia	348 (48.8)	708	76.0	187 (47.7)	385	77.7
Pre-diabetes	278 (46.9)	539	69.6	127 (48.3)	225	67.3
Nasopharyngitis						
Normo-glycaemia	162 (22.7)	295	31.7	88 (22.4)	150	30.3
Pre-diabetes	119 (20.1)	185	23.9	45 (17.1)	66	19.8
Upper respiratory tract infection						
Normo-glycaemia	59 (8.3)	80	8.6	48 (12.2)	71	14.3
Pre-diabetes	55 (9.3)	78	10.1	32 (12.2)	45	13.5
Gastroenteritis						
Normo-glycaemia	46 (6.5)	54	5.8	13 (3.3)	19	3.8
Pre-diabetes	39 (6.6)	50	6.5	17 (6.5)	19	5.7
Sinusitis						
Normo-glycaemia	39 (5.5)	43	4.6	25 (6.4)	28	5.7
Pre-diabetes	32 (5.4)	41	5.3	11 (4.2)	12	3.6
Urinary tract infection						
Normo-glycaemia	44 (6.2)	54	5.8	18 (4.6)	21	4.2
Pre-diabetes	24 (4.0)	29	3.7	10 (3.8)	13	3.9
Bronchitis						
Normo-glycaemia	28 (3.9)	31	3.3	13 (3.3)	15	3.0
Pre-diabetes	19 (3.2)	21	2.7	12 (4.6)	13	3.9
Rhinitis						
Normo-glycaemia	8 (1.1)	12	1.3	5 (1.3)	7	1.4
Pre-diabetes	11 (1.9)	13	1.7	4 (1.5)	7	2.1
Cystitis						
Normo-glycaemia	11 (1.5)	12	1.3	3 (0.8)	3	0.6
Pre-diabetes	8 (1.3)	9	1.2	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pharyngitis						
Normo-glycaemia	1 (0.1)	1	0.1	5 (1.3)	5	1.0
Pre-diabetes	12 (2.0)	12	1.5	4 (1.5)	4	1.2
Laryngitis						
Normo-glycaemia	9 (1.3)	9	1.0	4 (1.0)	5	1.0
Pre-diabetes	5 (0.8)	5	0.6	0		
Tonsillitis						
Normo-glycaemia	8 (1.1)	11	1.2	7 (1.8)	9	1.8
Pre-diabetes	4 (0.7)	4	0.5	3 (1.1)	3	0.9
Tooth infection						
Normo-glycaemia	6 (0.8)	6	0.6	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	6	0.8	2 (0.8)	2	0.6
Pneumonia						
Normo-glycaemia	7 (1.0)	10	1.1	3 (0.8)	3	0.6
Pre-diabetes	4 (0.7)	4	0.5	5 (1.9)	5	1.5
Acute sinusitis						
Normo-glycaemia	8 (1.1)	8	0.9	6 (1.5)	7	1.4
Pre-diabetes	3 (0.5)	4	0.5	2 (0.8)	2	0.6
Vaginal infection						
Normo-glycaemia	8 (1.1)	10	1.1	0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Ear infection						
Normo-glycaemia	4 (0.6)	5	0.5	2 (0.5)	2	0.4
Pre-diabetes	5 (0.8)	6	0.8	1 (0.4)	1	0.3
Lower respiratory tract infection						
Normo-glycaemia	4 (0.6)	4	0.4	6 (1.5)	7	1.4
Pre-diabetes	5 (0.8)	6	0.8	6 (2.3)	9	2.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tooth abscess						
Normo-glycaemia	6 (0.8)	6	0.6	5 (1.3)	6	1.2
Pre-diabetes	2 (0.3)	2	0.3	3 (1.1)	3	0.9
Conjunctivitis						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	4 (0.7)	4	0.5	1 (0.4)	1	0.3
Otitis media						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	0		
Eye infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	4 (0.7)	4	0.5	0		
Gastrointestinal infection						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	4 (0.7)	6	0.8	1 (0.4)	1	0.3
Pulpitis dental						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Appendicitis						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Folliculitis						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Gingivitis						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Chronic sinusitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Infected bite						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	0		
Pharyngotonsillitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	2	0.6
Breast abscess						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hordeolum						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Kidney infection						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pyelonephritis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Subcutaneous abscess						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Abdominal wall abscess						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Omphalitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Otitis externa						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Periodontitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Postoperative wound infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Abscess						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Atypical pneumonia						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Diarrhoea infectious						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	2	0.6
Localised infection						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abdominal abscess						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Device related infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Diverticulitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Endometritis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Fracture infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Haematoma infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Large intestine infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Mastitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oral infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Osteomyelitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Paronychia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Perirectal abscess						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Peritonitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Sepsis syndrome						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin infection						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Abscess limb						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Appendicitis perforated						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bartholinitis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Carbuncle						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Epididymitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Eyelid infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Groin abscess						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nail infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Oophoritis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Parasitic gastroenteritis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Parotitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Prostate infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Purulence								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Respiratory tract infection								
Normo-glycaemia	1	(0.1)	1	0.1	1	(0.3)	1	0.2
Pre-diabetes	0				0			
Salpingitis								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Arthritis infective								
Normo-glycaemia	0				0			
Pre-diabetes	0				1	(0.4)	1	0.3
Cervicitis								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Empyema								
Normo-glycaemia	0				0			
Pre-diabetes	0				1	(0.4)	1	0.3
Gastric infection								
Normo-glycaemia	0				0			
Pre-diabetes	0				1	(0.4)	1	0.3
Infected dermal cyst								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Lymphangitis								
Normo-glycaemia	0				0			
Pre-diabetes	0				1	(0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Neutropenic sepsis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Otitis media acute						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Peritonsillar abscess						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Peritonsillitis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Root canal infection						
Normo-glycaemia	0			0		
Pre-diabetes	0			2 (0.8)	2	0.6
Septic shock						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Tracheitis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Wound infection						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Viral infectious disorders						
Normo-glycaemia	107 (15.0)	139	14.9	50 (12.8)	67	13.5
Pre-diabetes	87 (14.7)	109	14.1	53 (20.2)	69	20.7

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Influenza						
Normo-glycaemia	56 (7.9)	71	7.6	27 (6.9)	35	7.1
Pre-diabetes	33 (5.6)	41	5.3	36 (13.7)	44	13.2
Gastroenteritis viral						
Normo-glycaemia	23 (3.2)	24	2.6	8 (2.0)	9	1.8
Pre-diabetes	19 (3.2)	20	2.6	6 (2.3)	6	1.8
Viral infection						
Normo-glycaemia	4 (0.6)	7	0.8	5 (1.3)	5	1.0
Pre-diabetes	10 (1.7)	13	1.7	3 (1.1)	3	0.9
Herpes zoster						
Normo-glycaemia	7 (1.0)	7	0.8	8 (2.0)	8	1.6
Pre-diabetes	5 (0.8)	6	0.8	3 (1.1)	3	0.9
Gastrointestinal viral infection						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	4 (0.7)	5	0.6	1 (0.4)	1	0.3
Viral upper respiratory tract infection						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	6	0.8	2 (0.8)	3	0.9
Ear infection viral						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	0		
Gastroenteritis norovirus						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Oral herpes						
Normo-glycaemia	2 (0.3)	3	0.3	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Herpes simplex						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	0			0		
Viral pharyngitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Dengue fever						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Respiratory tract infection viral						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Herpes virus infection						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Cytomegalovirus infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hepatitis E						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Papilloma viral infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Parainfluenzae virus infection						
Normo-glycaemia	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Respiratory syncytial virus infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Varicella						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Viral sinusitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Chronic hepatitis B						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastroenteritis astroviral						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Genital herpes zoster						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Infectious mononucleosis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Oral viral infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Vestibular neuronitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bronchitis viral						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Conjunctivitis viral						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hand-foot-and-mouth disease						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Meningitis viral						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Viral rhinitis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Bacterial infectious disorders						
Normo-glycaemia	26 (3.6)	31	3.3	16 (4.1)	17	3.4
Pre-diabetes	31 (5.2)	32	4.1	11 (4.2)	14	4.2
Pharyngitis streptococcal						
Normo-glycaemia	4 (0.6)	4	0.4	6 (1.5)	6	1.2
Pre-diabetes	7 (1.2)	7	0.9	0		
Cellulitis						
Normo-glycaemia	5 (0.7)	5	0.5	4 (1.0)	5	1.0
Pre-diabetes	4 (0.7)	4	0.5	3 (1.1)	3	0.9
Ear infection bacterial						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	0		
Helicobacter infection						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Bacterial vaginosis						
Normo-glycaemia	3 (0.4)	6	0.6	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Erysipelas						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Staphylococcal infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Furuncle						
Normo-glycaemia	2 (0.3)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Helicobacter gastritis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Bacterial colitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Lyme disease						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pharyngitis bacterial						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Salmonellosis								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Sinusitis bacterial								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Syphilis								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Bacterial vulvovaginitis								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Genital infection bacterial								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Skin bacterial infection								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Tonsillitis bacterial								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Typhoid fever								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				1	(0.4)	1	0.3
Bacteriuria								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Gastric ulcer helicobacter						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Listeriosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Staphylococcal sepsis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Streptococcal urinary tract infection						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Upper respiratory tract infection bacterial						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Fungal infectious disorders						
Normo-glycaemia	22 (3.1)	26	2.8	11 (2.8)	13	2.6
Pre-diabetes	23 (3.9)	27	3.5	11 (4.2)	11	3.3
Vulvovaginal mycotic infection						
Normo-glycaemia	5 (0.7)	5	0.5	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	8	1.0	0		
Fungal infection						
Normo-glycaemia	8 (1.1)	9	1.0	4 (1.0)	4	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Tinea pedis						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	0		
Vulvovaginal candidiasis						
Normo-glycaemia	4 (0.6)	6	0.6	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	2	0.3	2 (0.8)	2	0.6
Dermatophytosis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Skin candida						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Body tinea						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Fungal skin infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Onychomycosis						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	3 (1.1)	3	0.9
Candida infection						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Tinea capitis						
Normo-glycaemia	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Tinea cruris						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tinea infection						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dermatophytosis of nail						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Oral candidiasis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Otitis externa fungal						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Protozoal infectious disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Trichomoniasis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Toxoplasmosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Chlamydial infectious disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Chlamydial infection						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Ectoparasitic disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Acarodermatitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nervous system disorders						
Normo-glycaemia	210 (29.5)	382	41.0	83 (21.2)	134	27.0
Pre-diabetes	181 (30.5)	376	48.6	58 (22.1)	88	26.3
Headaches						
Normo-glycaemia	124 (17.4)	235	25.2	57 (14.5)	74	14.9
Pre-diabetes	105 (17.7)	216	27.9	32 (12.2)	44	13.2
Headache						
Normo-glycaemia	106 (14.9)	190	20.4	51 (13.0)	67	13.5
Pre-diabetes	92 (15.5)	197	25.4	29 (11.0)	37	11.1
Migraine						
Normo-glycaemia	21 (2.9)	39	4.2	4 (1.0)	4	0.8
Pre-diabetes	11 (1.9)	13	1.7	5 (1.9)	7	2.1
Sinus headache						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	0		
Tension headache						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Migraine with aura						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Occipital neuralgia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Neurological disorders NEC						
Normo-glycaemia	90 (12.6)	115	12.3	27 (6.9)	43	8.7
Pre-diabetes	91 (15.3)	133	17.2	20 (7.6)	25	7.5
Dizziness						
Normo-glycaemia	49 (6.9)	58	6.2	16 (4.1)	23	4.6
Pre-diabetes	49 (8.3)	72	9.3	7 (2.7)	12	3.6
Dysgeusia						
Normo-glycaemia	11 (1.5)	14	1.5	3 (0.8)	10	2.0
Pre-diabetes	7 (1.2)	10	1.3	1 (0.4)	1	0.3
Paraesthesia						
Normo-glycaemia	6 (0.8)	7	0.8	3 (0.8)	3	0.6
Pre-diabetes	7 (1.2)	10	1.3	2 (0.8)	2	0.6
Syncope						
Normo-glycaemia	6 (0.8)	6	0.6	1 (0.3)	1	0.2
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	1	0.3
Taste disorder						
Normo-glycaemia	3 (0.4)	5	0.5	1 (0.3)	1	0.2
Pre-diabetes	6 (1.0)	6	0.8	0		
Somnolence						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	5 (0.8)	7	0.9	1 (0.4)	1	0.3
Lethargy						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	2	0.6
Hypoaesthesia						
Normo-glycaemia	6 (0.8)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Neuralgia						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Hyperaesthesia						
Normo-glycaemia	2 (0.3)	4	0.4	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Dizziness postural						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Allodynia						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Burning sensation						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Presyncope						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Balance disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Ageusia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Aphasia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dysaesthesia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dysarthria						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hyporeflexia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Restless legs syndrome						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	2 (0.8)	2	0.6
Vertigo CNS origin						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Loss of consciousness						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Sensory disturbance						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Sensory loss						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Spinal cord and nerve root disorders						
Normo-glycaemia	11 (1.5)	12	1.3	5 (1.3)	5	1.0
Pre-diabetes	9 (1.5)	10	1.3	9 (3.4)	9	2.7
Sciatica						
Normo-glycaemia	7 (1.0)	8	0.9	3 (0.8)	3	0.6
Pre-diabetes	7 (1.2)	8	1.0	5 (1.9)	5	1.5
Cervicobrachial syndrome						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	0			2 (0.8)	2	0.6
Lumbar radiculopathy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Lumbosacral radiculopathy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Cervical radiculopathy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Spinal cord compression						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Peripheral neuropathies						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	9 (1.3)	9	1.0	4 (1.0)	4	0.8
Pre-diabetes	3 (0.5)	4	0.5	4 (1.5)	5	1.5
Neuropathy peripheral						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Carpal tunnel syndrome						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
Nerve compression						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Peripheral sensory neuropathy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Peroneal nerve palsy						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Radial nerve compression						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Movement disorders (incl parkinsonism)						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	2	0.4
Pre-diabetes	4 (0.7)	4	0.5	1 (0.4)	1	0.3
Tremor						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Essential tremor						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Mental impairment disorders						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Memory impairment						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Amnesia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dementia Alzheimer's type						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Disturbance in attention						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	3	0.6
Pre-diabetes	0			1 (0.4)	1	0.3
Cranial nerve disorders (excl neoplasms)						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Anosmia						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Parosmia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cranial nerve disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Sleep disturbances (incl subtypes)						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Poor quality sleep						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Increased intracranial pressure and hydrocephalus						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Idiopathic intracranial hypertension						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Central nervous system vascular disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Cerebral infarction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Ischaemic stroke						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Neurological disorders of the eye						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Visual field defect						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Neuromuscular disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Autonomic nervous system imbalance						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Demyelinating disorders						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Multiple sclerosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Seizures (incl subtypes)						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Partial seizures						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Psychogenic seizure						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue disorders						
Normo-glycaemia	174 (24.4)	291	31.2	99 (25.3)	161	32.5
Pre-diabetes	164 (27.7)	267	34.5	87 (33.1)	143	42.8
Musculoskeletal and connective tissue disorders NEC						
Normo-glycaemia	97 (13.6)	129	13.8	55 (14.0)	78	15.7
Pre-diabetes	90 (15.2)	115	14.8	44 (16.7)	54	16.2
Back pain						
Normo-glycaemia	62 (8.7)	72	7.7	28 (7.1)	30	6.1
Pre-diabetes	45 (7.6)	49	6.3	26 (9.9)	26	7.8
Pain in extremity						
Normo-glycaemia	18 (2.5)	19	2.0	12 (3.1)	14	2.8
Pre-diabetes	26 (4.4)	29	3.7	12 (4.6)	14	4.2
Musculoskeletal pain						
Normo-glycaemia	21 (2.9)	21	2.3	8 (2.0)	10	2.0
Pre-diabetes	10 (1.7)	10	1.3	8 (3.0)	8	2.4
Neck pain						
Normo-glycaemia	5 (0.7)	6	0.6	9 (2.3)	9	1.8
Pre-diabetes	14 (2.4)	15	1.9	0		
Musculoskeletal chest pain						
Normo-glycaemia	5 (0.7)	5	0.5	3 (0.8)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	2 (0.8)	2	0.6
Musculoskeletal stiffness						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	0		
Flank pain						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Plantar fasciitis						
Normo-glycaemia	2 (0.3)	2	0.2	5 (1.3)	6	1.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Axillary mass						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Dupuytren's contracture						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Musculoskeletal discomfort						
Normo-glycaemia	1 (0.1)	2	0.2	0		
Pre-diabetes	0			0		
Groin pain						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Limb mass						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	0			0		
Muscle contracture						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			2 (0.8)	2	0.6
Neck mass						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Joint disorders						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	67 (9.4)	85	9.1	36 (9.2)	42	8.5
Pre-diabetes	66 (11.1)	84	10.8	39 (14.8)	52	15.6
Arthralgia						
Normo-glycaemia	41 (5.8)	49	5.3	22 (5.6)	23	4.6
Pre-diabetes	40 (6.7)	43	5.6	21 (8.0)	24	7.2
Osteoarthritis						
Normo-glycaemia	11 (1.5)	11	1.2	7 (1.8)	7	1.4
Pre-diabetes	12 (2.0)	17	2.2	11 (4.2)	13	3.9
Spinal osteoarthritis						
Normo-glycaemia	7 (1.0)	7	0.8	0		
Pre-diabetes	5 (0.8)	6	0.8	0		
Arthritis						
Normo-glycaemia	5 (0.7)	5	0.5	3 (0.8)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	3 (1.1)	3	0.9
Joint swelling						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	3 (1.1)	3	0.9
Rotator cuff syndrome						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	2 (0.8)	2	0.6
Joint stiffness						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Vertebral foraminal stenosis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	3	0.4	0		
Facet joint syndrome						

Adverse events with onset prior to randomisation are not included.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Vertebral osteophyte						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Arthropathy						
Normo-glycaemia	1 (0.1)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Periarthritis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	2	0.4
Pre-diabetes	0			0		
Spondylitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Chondromalacia						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Haemarthrosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Joint noise						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Joint range of motion decreased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Joint space narrowing						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Polyarthritis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Rheumatoid arthritis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Spondyloarthropathy						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Muscle disorders						
Normo-glycaemia	28 (3.9)	32	3.4	12 (3.1)	17	3.4
Pre-diabetes	30 (5.1)	32	4.1	11 (4.2)	12	3.6
Myalgia						
Normo-glycaemia	10 (1.4)	12	1.3	3 (0.8)	8	1.6
Pre-diabetes	13 (2.2)	14	1.8	5 (1.9)	5	1.5
Muscle spasms						
Normo-glycaemia	11 (1.5)	11	1.2	6 (1.5)	6	1.2
Pre-diabetes	8 (1.3)	8	1.0	4 (1.5)	5	1.5
Muscular weakness						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	3 (0.5)	4	0.5	1 (0.4)	1	0.3
Fibromyalgia						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Myofascial pain syndrome						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Muscle tightness						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Myalgia intercostal						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Myosclerosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Torticollis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Muscle disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Muscle fatigue						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Muscle twitching						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Tendon, ligament and cartilage disorders						
Normo-glycaemia	17 (2.4)	19	2.0	7 (1.8)	8	1.6
Pre-diabetes	8 (1.3)	8	1.0	6 (2.3)	7	2.1

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tendonitis						
Normo-glycaemia	8 (1.1)	9	1.0	5 (1.3)	6	1.2
Pre-diabetes	5 (0.8)	5	0.6	4 (1.5)	5	1.5
Tenosynovitis						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Costochondritis						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			0		
Tendon disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Osteochondrosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Posterior tibial tendon dysfunction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Tendon discomfort						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Tendon pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Trigger finger						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			2 (0.8)	2	0.6

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)						
Normo-glycaemia	10 (1.4)	15	1.6	2 (0.5)	3	0.6
Pre-diabetes	9 (1.5)	9	1.2	9 (3.4)	10	3.0
Intervertebral disc protrusion						
Normo-glycaemia	5 (0.7)	5	0.5	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	3 (1.1)	4	1.2
Intervertebral disc degeneration						
Normo-glycaemia	4 (0.6)	6	0.6	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Scoliosis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Cervical spinal stenosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Finger deformity						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Spinal stenosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Intervertebral disc displacement						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Kyphoscoliosis						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Spondylolisthesis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Foot deformity						
Normo-glycaemia	0			0		
Pre-diabetes	0			3 (1.1)	3	0.9
Intervertebral disc annular tear						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Kyphosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Synovial and bursal disorders						
Normo-glycaemia	8 (1.1)	8	0.9	2 (0.5)	2	0.4
Pre-diabetes	8 (1.3)	8	1.0	3 (1.1)	3	0.9
Bursitis						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2
Pre-diabetes	6 (1.0)	6	0.8	2 (0.8)	2	0.6
Synovial cyst						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Synovitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bursal fluid accumulation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Bone disorders (excl congenital and fractures)						
Normo-glycaemia	2 (0.3)	2	0.2	9 (2.3)	9	1.8
Pre-diabetes	9 (1.5)	10	1.3	5 (1.9)	5	1.5
Osteopenia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Pain in jaw						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	0		
Bone cyst						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Coccydynia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Metatarsalgia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Osteonecrosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Exostosis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Osteoporosis								
Normo-glycaemia	1	(0.1)	1	0.1	3	(0.8)	3	0.6
Pre-diabetes	0				0			
Pubic pain								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Connective tissue disorders (excl congenital)								
Normo-glycaemia	1	(0.1)	1	0.1	2	(0.5)	2	0.4
Pre-diabetes	1	(0.2)	1	0.1	0			
Myofascitis								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Sjogren's syndrome								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Systemic lupus erythematosus								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Systemic scleroderma								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
General disorders and administration site conditions								
Normo-glycaemia	164	(23.0)	255	27.4	75	(19.1)	125	25.2
Pre-diabetes	127	(21.4)	210	27.1	56	(21.3)	97	29.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
General system disorders NEC						
Normo-glycaemia	126 (17.7)	176	18.9	45 (11.5)	58	11.7
Pre-diabetes	99 (16.7)	148	19.1	41 (15.6)	55	16.5
Fatigue						
Normo-glycaemia	59 (8.3)	69	7.4	19 (4.8)	19	3.8
Pre-diabetes	45 (7.6)	51	6.6	9 (3.4)	10	3.0
Asthenia						
Normo-glycaemia	16 (2.2)	19	2.0	6 (1.5)	7	1.4
Pre-diabetes	19 (3.2)	34	4.4	5 (1.9)	5	1.5
Early satiety						
Normo-glycaemia	21 (2.9)	21	2.3	2 (0.5)	2	0.4
Pre-diabetes	5 (0.8)	5	0.6	0		
Pain						
Normo-glycaemia	12 (1.7)	12	1.3	3 (0.8)	3	0.6
Pre-diabetes	9 (1.5)	11	1.4	4 (1.5)	4	1.2
Influenza like illness						
Normo-glycaemia	11 (1.5)	12	1.3	5 (1.3)	5	1.0
Pre-diabetes	6 (1.0)	6	0.8	8 (3.0)	8	2.4
Malaise						
Normo-glycaemia	12 (1.7)	14	1.5	0		
Pre-diabetes	4 (0.7)	5	0.6	4 (1.5)	5	1.5
Chest discomfort						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	7 (1.2)	7	0.9	1 (0.4)	2	0.6
Chills						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	7 (1.2)	7	0.9	1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Non-cardiac chest pain						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	3 (1.1)	3	0.9
Hunger						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Oedema peripheral						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	5 (1.9)	5	1.5
Chest pain						
Normo-glycaemia	1 (0.1)	1	0.1	5 (1.3)	5	1.0
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Thirst						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Feeling hot						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Swelling						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Hernia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Peripheral swelling						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Swelling face						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Feeling cold						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Ill-defined disorder						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Sensation of foreign body						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Axillary pain						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hangover						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Inflammation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
Crying						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Fat tissue increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pseudocyst						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Sense of oppression						
Normo-glycaemia	1 (0.1)	2	0.2	0		
Pre-diabetes	0			0		
Sluggishness						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Discomfort						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Facial pain						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Granuloma						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Gravitational oedema						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Temperature intolerance						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Administration site reactions						
Normo-glycaemia	35 (4.9)	50	5.4	27 (6.9)	52	10.5
Pre-diabetes	30 (5.1)	49	6.3	17 (6.5)	30	9.0

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Injection site bruising						
Normo-glycaemia	15 (2.1)	16	1.7	16 (4.1)	21	4.2
Pre-diabetes	13 (2.2)	15	1.9	10 (3.8)	13	3.9
Injection site pain						
Normo-glycaemia	10 (1.4)	11	1.2	10 (2.6)	12	2.4
Pre-diabetes	9 (1.5)	13	1.7	6 (2.3)	9	2.7
Injection site pruritus						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	6 (1.0)	6	0.8	0		
Injection site mass						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Injection site reaction						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Injection site erythema						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Injection site haematoma						
Normo-glycaemia	3 (0.4)	8	0.9	1 (0.3)	9	1.8
Pre-diabetes	0			3 (1.1)	3	0.9
Injection site haemorrhage						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Injection site inflammation						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	4	0.5	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Injection site paraesthesia						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Application site haematoma						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Infusion site extravasation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Injection site swelling						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Injection site urticaria						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Vessel puncture site rash						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Injection site induration						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Vessel puncture site bruise						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Application site bruise						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Puncture site pain						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	0			0		
Body temperature conditions						
Normo-glycaemia	19 (2.7)	25	2.7	12 (3.1)	13	2.6
Pre-diabetes	8 (1.3)	8	1.0	5 (1.9)	8	2.4
Pyrexia						
Normo-glycaemia	19 (2.7)	25	2.7	12 (3.1)	13	2.6
Pre-diabetes	8 (1.3)	8	1.0	5 (1.9)	8	2.4
Tissue disorders NEC						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	3 (1.1)	3	0.9
Cyst						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Nodule						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Dysplasia						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Fat necrosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hyperplasia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Therapeutic and nontherapeutic effects (excl toxicity)						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Withdrawal syndrome						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Complications associated with device						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Vascular stent occlusion						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Injury associated with device						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Metabolism and nutrition disorders						
Normo-glycaemia	101 (14.2)	134	14.4	45 (11.5)	61	12.3
Pre-diabetes	98 (16.5)	133	17.2	38 (14.4)	47	14.1
Appetite and general nutritional disorders						
Normo-glycaemia	79 (11.1)	100	10.7	16 (4.1)	22	4.4
Pre-diabetes	62 (10.5)	72	9.3	12 (4.6)	14	4.2
Decreased appetite						
Normo-glycaemia	73 (10.2)	83	8.9	12 (3.1)	14	2.8
Pre-diabetes	51 (8.6)	56	7.2	10 (3.8)	12	3.6

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Food craving						
Normo-glycaemia	5 (0.7)	5	0.5	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	0		
Hyperphagia						
Normo-glycaemia	3 (0.4)	4	0.4	1 (0.3)	3	0.6
Pre-diabetes	4 (0.7)	4	0.5	1 (0.4)	1	0.3
Increased appetite						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	5	0.6	1 (0.4)	1	0.3
Food aversion						
Normo-glycaemia	2 (0.3)	4	0.4	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Lack of satiety						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Malnutrition						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Vitamin related disorders						
Normo-glycaemia	10 (1.4)	11	1.2	6 (1.5)	7	1.4
Pre-diabetes	12 (2.0)	17	2.2	4 (1.5)	5	1.5
Vitamin D deficiency						
Normo-glycaemia	7 (1.0)	7	0.8	5 (1.3)	5	1.0
Pre-diabetes	10 (1.7)	10	1.3	3 (1.1)	3	0.9
Vitamin B12 deficiency						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	2 (0.3)	2	0.3	0		

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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Folate deficiency						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Vitamin A deficiency						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Vitamin B complex deficiency						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Vitamin B2 deficiency						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Lipid metabolism disorders						
Normo-glycaemia	9 (1.3)	9	1.0	12 (3.1)	13	2.6
Pre-diabetes	11 (1.9)	12	1.5	8 (3.0)	8	2.4
Dyslipidaemia						
Normo-glycaemia	5 (0.7)	5	0.5	5 (1.3)	6	1.2
Pre-diabetes	5 (0.8)	5	0.6	4 (1.5)	4	1.2
Hypercholesterolaemia						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	3 (1.1)	3	0.9
Hypertriglyceridaemia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Cholesterosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		

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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hyperlipidaemia						
Normo-glycaemia	0			4 (1.0)	4	0.8
Pre-diabetes	1 (0.2)	1	0.1	0		
Glucose metabolism disorders (incl diabetes mellitus)						
Normo-glycaemia	3 (0.4)	3	0.3	10 (2.6)	11	2.2
Pre-diabetes	7 (1.2)	14	1.8	11 (4.2)	14	4.2
Hypoglycaemia						
Normo-glycaemia	2 (0.3)	2	0.2	4 (1.0)	5	1.0
Pre-diabetes	5 (0.8)	11	1.4	1 (0.4)	2	0.6
Postprandial hypoglycaemia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Type 2 diabetes mellitus						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	6 (2.3)	7	2.1
Glucose tolerance impaired						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	0			1 (0.4)	1	0.3
Diabetes mellitus						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hyperglycaemia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Impaired fasting glucose						
Normo-glycaemia	0			2 (0.5)	2	0.4

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Insulin resistance						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Electrolyte and fluid balance conditions						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	9	1.2	4 (1.5)	4	1.2
Hypokalaemia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	4	0.5	2 (0.8)	2	0.6
Hyponatraemia						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Hyperkalaemia						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Dehydration						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Electrolyte imbalance						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Polydipsia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Fluid retention						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Iron and trace metal metabolism disorders						
Normo-glycaemia	2 (0.3)	2	0.2	4 (1.0)	4	0.8
Pre-diabetes	3 (0.5)	3	0.4	0		
Iron deficiency						
Normo-glycaemia	2 (0.3)	2	0.2	4 (1.0)	4	0.8
Pre-diabetes	3 (0.5)	3	0.4	0		
Purine and pyrimidine metabolism disorders						
Normo-glycaemia	1 (0.1)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	2 (0.8)	2	0.6
Gout						
Normo-glycaemia	1 (0.1)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Hyperuricaemia						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Food intolerance syndromes						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			0		
Dairy intolerance						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Food intolerance						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Pre-diabetes	0				0			
Lactose intolerance								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Metabolism disorders NEC								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Hyperlipasaemia								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Bone, calcium, magnesium and phosphorus metabolism disorders								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Hypomagnesaemia								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Protein and amino acid metabolism disorders NEC								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Hypoalbuminaemia								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Skin and subcutaneous tissue disorders								
Normo-glycaemia	92	(12.9)	119	12.8	42	(10.7)	53	10.7

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	96 (16.2)	130	16.8	33 (12.5)	43	12.9
Epidermal and dermal conditions						
Normo-glycaemia	48 (6.7)	53	5.7	28 (7.1)	37	7.5
Pre-diabetes	57 (9.6)	76	9.8	24 (9.1)	28	8.4
Rash						
Normo-glycaemia	7 (1.0)	7	0.8	11 (2.8)	15	3.0
Pre-diabetes	19 (3.2)	23	3.0	6 (2.3)	8	2.4
Pruritus						
Normo-glycaemia	10 (1.4)	11	1.2	2 (0.5)	2	0.4
Pre-diabetes	7 (1.2)	7	0.9	4 (1.5)	4	1.2
Eczema						
Normo-glycaemia	9 (1.3)	9	1.0	2 (0.5)	2	0.4
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	2	0.6
Dry skin						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	8 (1.3)	8	1.0	1 (0.4)	1	0.3
Skin burning sensation						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	4 (0.7)	10	1.3	2 (0.8)	2	0.6
Dermatitis contact						
Normo-glycaemia	4 (0.6)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Skin lesion						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Dermatitis						
Normo-glycaemia	0			0		

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	3 (0.5)	3	0.4	2 (0.8)	2	0.6
Rash pruritic						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Erythema						
Normo-glycaemia	1 (0.1)	1	0.1	4 (1.0)	4	0.8
Pre-diabetes	2 (0.3)	2	0.3	0		
Pain of skin						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Psoriasis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin irritation						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Blister						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	4 (1.5)	4	1.2
Decubitus ulcer						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dermatitis allergic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin disorder						
Normo-glycaemia	1 (0.1)	2	0.2	1 (0.3)	1	0.2

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Macule						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Papule						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pityriasis rosea						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Rash maculo-papular						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dermatitis atopic						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Perioral dermatitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Prurigo						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Skin discolouration						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	0			0		
Skin odour abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Xanthelasma						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Drug eruption						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Photosensitivity reaction						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Rash erythematous						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Rash macular						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Skin reaction						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Skin appendage conditions						
Normo-glycaemia	46 (6.5)	53	5.7	8 (2.0)	9	1.8
Pre-diabetes	36 (6.1)	39	5.0	11 (4.2)	12	3.6
Alopecia						
Normo-glycaemia	30 (4.2)	31	3.3	3 (0.8)	3	0.6
Pre-diabetes	23 (3.9)	24	3.1	2 (0.8)	2	0.6
Hyperhidrosis						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	3	0.6

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	4 (0.7)	4	0.5	5 (1.9)	5	1.5
Acne						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Hirsutism						
Normo-glycaemia	2 (0.3)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Ingrowing nail						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	2	0.6
Cold sweat						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			0		
Hair growth abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Miliaria						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Rosacea						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	2	0.3	1 (0.4)	1	0.3
Hidradenitis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Hypertrichosis						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Nail bed inflammation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Nail discolouration						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Onychoclasis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Diffuse alopecia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Night sweats						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Angioedema and urticaria						
Normo-glycaemia	7 (1.0)	7	0.8	3 (0.8)	3	0.6
Pre-diabetes	6 (1.0)	6	0.8	3 (1.1)	3	0.9
Urticaria						
Normo-glycaemia	6 (0.8)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	6	0.8	3 (1.1)	3	0.9
Cold urticaria						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Angioedema						
Normo-glycaemia	0			1 (0.3)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Cornification and dystrophic skin disorders						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	4 (0.7)	6	0.8	0		
Actinic keratosis						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	4	0.5	0		
Hyperkeratosis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Lichenoid keratosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Skin striae						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pigmentation disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Ephelides						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin hyperpigmentation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Cutaneous neoplasms benign						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Dermal cyst						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin vascular abnormalities						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Ecchymosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Skin and subcutaneous tissue disorders NEC						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	0			0		
Erythema nodosum						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Skin ulcer						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Injury, poisoning and procedural complications						
Normo-glycaemia	102 (14.3)	149	16.0	71 (18.1)	96	19.4
Pre-diabetes	86 (14.5)	115	14.8	50 (19.0)	80	23.9
Injuries NEC						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	62 (8.7)	89	9.6	54 (13.8)	71	14.3
Pre-diabetes	64 (10.8)	79	10.2	42 (16.0)	59	17.7
Ligament sprain						
Normo-glycaemia	10 (1.4)	13	1.4	12 (3.1)	12	2.4
Pre-diabetes	11 (1.9)	11	1.4	7 (2.7)	8	2.4
Fall						
Normo-glycaemia	13 (1.8)	13	1.4	6 (1.5)	10	2.0
Pre-diabetes	6 (1.0)	6	0.8	6 (2.3)	9	2.7
Muscle strain						
Normo-glycaemia	11 (1.5)	11	1.2	9 (2.3)	9	1.8
Pre-diabetes	6 (1.0)	7	0.9	6 (2.3)	6	1.8
Contusion						
Normo-glycaemia	9 (1.3)	12	1.3	6 (1.5)	6	1.2
Pre-diabetes	6 (1.0)	7	0.9	9 (3.4)	13	3.9
Arthropod bite						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	6 (1.0)	6	0.8	4 (1.5)	4	1.2
Skin laceration						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	4	0.8
Pre-diabetes	5 (0.8)	5	0.6	5 (1.9)	5	1.5
Limb injury						
Normo-glycaemia	1 (0.1)	1	0.1	4 (1.0)	4	0.8
Pre-diabetes	5 (0.8)	5	0.6	0		
Arthropod sting						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	0		
Skin abrasion						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	5	0.5	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	2 (0.8)	2	0.6
Tooth fracture						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Ligament rupture						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Concussion						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Epicondylitis						
Normo-glycaemia	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Road traffic accident						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Muscle rupture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Animal bite						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Back injury						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Wound						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Injury						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Bone contusion						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Muscle injury						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Musculoskeletal injury						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Nerve injury						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Post-traumatic pain						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skeletal injury						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Soft tissue foreign body						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Subdural haematoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Eye burns						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Eyelid contusion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Eyelid injury						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Face injury						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Foreign body in eye						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Head injury						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Ligament injury						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Post-traumatic neck syndrome						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Tendon injury						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Chest injury						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Corneal abrasion						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Eye injury						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Gun shot wound						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Post concussion syndrome						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Scar						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Tendon rupture						
Normo-glycaemia	0			2 (0.5)	3	0.6
Pre-diabetes	0			0		
Bone and joint injuries						
Normo-glycaemia	22 (3.1)	24	2.6	11 (2.8)	11	2.2
Pre-diabetes	13 (2.2)	15	1.9	11 (4.2)	12	3.6
Joint injury						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Foot fracture						
Normo-glycaemia	4 (0.6)	6	0.6	4 (1.0)	4	0.8
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Meniscus injury						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	4 (1.5)	5	1.5
Radius fracture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Rib fracture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Hand fracture						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Joint dislocation						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Facial bones fracture						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Femur fracture						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Fractured coccyx						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Thoracic vertebral fracture						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tibia fracture						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Ankle fracture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Spinal compression fracture						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Stress fracture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Upper limb fracture						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Wrist fracture						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Fibula fracture						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Torus fracture						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Procedural related injuries and complications NEC						
Normo-glycaemia	14 (2.0)	20	2.1	5 (1.3)	6	1.2
Pre-diabetes	13 (2.2)	15	1.9	6 (2.3)	7	2.1
Procedural pain						
Normo-glycaemia	7 (1.0)	7	0.8	2 (0.5)	3	0.6
Pre-diabetes	5 (0.8)	6	0.8	5 (1.9)	6	1.8
Injection related reaction						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Post procedural complication						
Normo-glycaemia	3 (0.4)	4	0.4	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Administration related reaction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Procedural nausea						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Post procedural haemorrhage						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Procedural haemorrhage						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Suture related complication						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Vaccination complication						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Anaemia postoperative						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Anaphylactic transfusion reaction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Post procedural constipation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Urinary retention postoperative						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Procedural vomiting						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Seroma						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Medication errors and other product use errors and issues						
Normo-glycaemia	7 (1.0)	7	0.8	2 (0.5)	3	0.6

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	3 (0.5)	3	0.4	0		
Accidental overdose						
Normo-glycaemia	5 (0.7)	5	0.5	2 (0.5)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	0		
Incorrect dose administered						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Medication error						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Injuries by physical agents						
Normo-glycaemia	5 (0.7)	5	0.5	3 (0.8)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Sunburn						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Heat illness						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Heat exhaustion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Hypobarism						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Thermal burn						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Burns second degree						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	0			1 (0.4)	1	0.3
Overdoses and underdoses NEC						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Overdose						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Exposures, chemical injuries and poisoning						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Reactive gastropathy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Exposure to toxic agent						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Respiratory, thoracic and mediastinal disorders						
Normo-glycaemia	101 (14.2)	137	14.7	57 (14.5)	68	13.7
Pre-diabetes	72 (12.1)	88	11.4	47 (17.9)	66	19.8
Respiratory tract signs and symptoms						
Normo-glycaemia	46 (6.5)	51	5.5	16 (4.1)	19	3.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	29 (4.9)	30	3.9	17 (6.5)	18	5.4
Oropharyngeal pain						
Normo-glycaemia	35 (4.9)	40	4.3	12 (3.1)	14	2.8
Pre-diabetes	13 (2.2)	13	1.7	11 (4.2)	12	3.6
Rhinorrhoea						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Upper respiratory tract inflammation						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	3 (0.5)	4	0.5	4 (1.5)	4	1.2
Hiccups						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Upper-airway cough syndrome						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Catarrh						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Dysphonia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Diaphragmalgia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Oropharyngeal discomfort						
Normo-glycaemia	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Paranasal sinus discomfort						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	0			0		
Pleuritic pain						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Sinus pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Yawning						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Upper respiratory tract congestion						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Respiratory disorders NEC						
Normo-glycaemia	37 (5.2)	45	4.8	27 (6.9)	30	6.1
Pre-diabetes	24 (4.0)	25	3.2	24 (9.1)	26	7.8
Cough						
Normo-glycaemia	25 (3.5)	30	3.2	17 (4.3)	18	3.6
Pre-diabetes	15 (2.5)	15	1.9	16 (6.1)	17	5.1
Dyspnoea						
Normo-glycaemia	6 (0.8)	6	0.6	6 (1.5)	6	1.2
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Sleep apnoea syndrome						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	2	0.6
Productive cough						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Haemoptysis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Dyspnoea exertional						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Respiratory disorder						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	0			1 (0.4)	1	0.3
Hyperventilation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Respiratory tract congestion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Acute respiratory failure						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Pulmonary mass						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Upper respiratory tract disorders (excl infections)						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	25 (3.5)	26	2.8	10 (2.6)	13	2.6
Pre-diabetes	26 (4.4)	27	3.5	8 (3.0)	8	2.4
Sinus congestion						
Normo-glycaemia	8 (1.1)	8	0.9	4 (1.0)	6	1.2
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	1	0.3
Nasal congestion						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	3	0.6
Pre-diabetes	7 (1.2)	7	0.9	3 (1.1)	3	0.9
Rhinitis allergic						
Normo-glycaemia	8 (1.1)	8	0.9	2 (0.5)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	4 (1.5)	4	1.2
Epistaxis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	5 (0.8)	5	0.6	0		
Nasal polyps						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Nasal septum deviation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Paranasal sinus hypersecretion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tonsillar hypertrophy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Nasal dryness						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Vocal cord polyp						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Paranasal cyst						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nasal adhesions						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Bronchial disorders (excl neoplasms)						
Normo-glycaemia	13 (1.8)	13	1.4	5 (1.3)	5	1.0
Pre-diabetes	1 (0.2)	1	0.1	8 (3.0)	11	3.3
Asthma						
Normo-glycaemia	11 (1.5)	11	1.2	5 (1.3)	5	1.0
Pre-diabetes	0			4 (1.5)	6	1.8
Chronic obstructive pulmonary disease						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Wheezing						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Allergic bronchitis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	2	0.6

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Lower respiratory tract disorders (excl obstruction and infection)						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Atelectasis						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Pulmonary fibrosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pleural disorders						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Pleural effusion						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Pleurisy						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Pulmonary vascular disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			2 (0.8)	2	0.6
Pulmonary embolism						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			2 (0.8)	2	0.6
Psychiatric disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	72 (10.1)	92	9.9	54 (13.8)	76	15.3
Pre-diabetes	52 (8.8)	68	8.8	29 (11.0)	37	11.1
Anxiety disorders and symptoms						
Normo-glycaemia	29 (4.1)	30	3.2	21 (5.4)	22	4.4
Pre-diabetes	17 (2.9)	18	2.3	10 (3.8)	10	3.0
Anxiety						
Normo-glycaemia	18 (2.5)	19	2.0	11 (2.8)	11	2.2
Pre-diabetes	14 (2.4)	14	1.8	9 (3.4)	9	2.7
Stress						
Normo-glycaemia	6 (0.8)	6	0.6	5 (1.3)	5	1.0
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Panic attack						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Post-traumatic stress disorder						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Acute stress disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Burnout syndrome						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nervousness						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Agitation						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	0			0		
Generalised anxiety disorder						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Sleep disorders and disturbances						
Normo-glycaemia	19 (2.7)	21	2.3	17 (4.3)	19	3.8
Pre-diabetes	21 (3.5)	21	2.7	12 (4.6)	14	4.2
Insomnia						
Normo-glycaemia	15 (2.1)	16	1.7	12 (3.1)	13	2.6
Pre-diabetes	13 (2.2)	13	1.7	6 (2.3)	6	1.8
Sleep disorder						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	5 (1.9)	6	1.8
Initial insomnia						
Normo-glycaemia	1 (0.1)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Abnormal dreams						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Middle insomnia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Nightmare						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Sleep terror						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Depressed mood disorders and disturbances						
Normo-glycaemia	22 (3.1)	25	2.7	18 (4.6)	20	4.0
Pre-diabetes	11 (1.9)	14	1.8	9 (3.4)	9	2.7
Depression						
Normo-glycaemia	10 (1.4)	11	1.2	10 (2.6)	11	2.2
Pre-diabetes	5 (0.8)	6	0.8	4 (1.5)	4	1.2
Depressed mood						
Normo-glycaemia	11 (1.5)	12	1.3	6 (1.5)	6	1.2
Pre-diabetes	3 (0.5)	3	0.4	3 (1.1)	3	0.9
Major depression						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Anhedonia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tearfulness						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Negative thoughts						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Depressive symptom						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Persistent depressive disorder						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			2 (0.8)	2	0.6
Mood disorders and disturbances NEC						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	5	0.6	0		
Irritability						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Apathy						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Affective disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Mood swings						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Sexual dysfunctions, disturbances and gender identity disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Libido decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Libido increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Changes in physical activity						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Restlessness						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Suicidal and self-injurious behaviours NEC						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	5	1.0
Pre-diabetes	1 (0.2)	1	0.1	0		
Suicidal ideation						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	4	0.8
Pre-diabetes	1 (0.2)	1	0.1	0		
Suicide attempt						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Adjustment disorders (incl subtypes)						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Adjustment disorder						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Grief reaction						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Adjustment disorder with depressed mood						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	0			0		
Cognitive and attention disorders and disturbances						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	2	0.3	0		
Mental fatigue						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Attention deficit/hyperactivity disorder						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Manic and bipolar mood disorders and disturbances						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Bipolar disorder						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Psychiatric and behavioural symptoms NEC						
Normo-glycaemia	0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Abulia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Psychiatric symptom						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Deliria (incl confusion)						
Normo-glycaemia	1 (0.1)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Disorientation						
Normo-glycaemia	1 (0.1)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Psychiatric disorders NEC						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Alcoholic hangover						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Somatic symptom and related disorders						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Conversion disorder						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Reproductive system and breast disorders						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	60 (8.4)	75	8.1	20 (5.1)	26	5.2
Pre-diabetes	36 (6.1)	47	6.1	12 (4.6)	13	3.9
Menstrual cycle and uterine bleeding disorders						
Normo-glycaemia	28 (3.9)	34	3.6	4 (1.0)	7	1.4
Pre-diabetes	17 (2.9)	19	2.5	3 (1.1)	3	0.9
Menstruation irregular						
Normo-glycaemia	9 (1.3)	9	1.0	0		
Pre-diabetes	5 (0.8)	5	0.6	0		
Menorrhagia						
Normo-glycaemia	7 (1.0)	8	0.9	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	4	0.5	2 (0.8)	2	0.6
Metrorrhagia						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Dysmenorrhoea						
Normo-glycaemia	5 (0.7)	6	0.6	1 (0.3)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	0		
Menstrual disorder						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dysfunctional uterine bleeding						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Menstruation delayed						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Oligomenorrhoea						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Amenorrhoea						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Premenstrual syndrome						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Premenstrual pain						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Breast disorders						
Normo-glycaemia	10 (1.4)	11	1.2	3 (0.8)	4	0.8
Pre-diabetes	7 (1.2)	9	1.2	4 (1.5)	4	1.2
Breast mass						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	2	0.4
Pre-diabetes	5 (0.8)	5	0.6	0		
Breast cyst						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Breast pain						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Breast disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Fibrocystic breast disease						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Breast inflammation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nipple pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Breast fibrosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Breast haematoma						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Uterine, pelvic and broad ligament disorders						
Normo-glycaemia	7 (1.0)	7	0.8	2 (0.5)	2	0.4
Pre-diabetes	4 (0.7)	4	0.5	0		
Uterine haemorrhage						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Endometriosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Adenomyosis						
Normo-glycaemia	2 (0.3)	2	0.2	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Uterine polyp						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Vaginal prolapse						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Uterine enlargement						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Menopause related conditions						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	4	0.8
Pre-diabetes	6 (1.0)	6	0.8	1 (0.4)	1	0.3
Atrophic vulvovaginitis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Menopausal symptoms						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	0		
Postmenopausal haemorrhage						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	2	0.4
Pre-diabetes	0			0		
Ovarian and fallopian tube disorders						
Normo-glycaemia	6 (0.8)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Ovarian cyst						
Normo-glycaemia	5 (0.7)	5	0.5	2 (0.5)	2	0.4

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (0.3)	2	0.3	0		
Hydrosalpinx						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Polycystic ovaries						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Vulvovaginal disorders (excl infections and inflammations)						
Normo-glycaemia	7 (1.0)	7	0.8	4 (1.0)	4	0.8
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Vaginal haemorrhage						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	0		
Vulvovaginal discomfort						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Vulvovaginal dryness						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Vulvovaginal pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Vaginal polyp						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Vulvovaginal pruritus						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Reproductive tract disorders NEC						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Pelvic pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Genital rash						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Genital pain						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Cervix disorders (excl infections and inflammations)						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Cervical leukoplakia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Cervical dysplasia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Uterine cervical erosion						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Testicular and epididymal disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Testicular mass						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Testicular pain						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Testicular disorder						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Sexual function and fertility disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Dyspareunia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Erectile dysfunction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Female reproductive tract infections and inflammations						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Uterine inflammation						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Prostatic disorders (excl infections and inflammations)						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Benign prostatic hyperplasia						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Penile and scrotal disorders (excl infections and inflammations)						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Scrotal pain						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Investigations						
Normo-glycaemia	43 (6.0)	60	6.4	21 (5.4)	30	6.1
Pre-diabetes	50 (8.4)	58	7.5	28 (10.6)	37	11.1
Hepatobiliary investigations						
Normo-glycaemia	9 (1.3)	9	1.0	5 (1.3)	6	1.2
Pre-diabetes	7 (1.2)	8	1.0	6 (2.3)	9	2.7
Gamma-glutamyltransferase increased						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	5 (0.8)	5	0.6	2 (0.8)	2	0.6
Hepatic enzyme increased						

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	0		
Alanine aminotransferase increased						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Aspartate aminotransferase increased						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			3 (1.1)	3	0.9
Blood bilirubin increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			2 (0.8)	2	0.6
Transaminases increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Gastrointestinal investigations						
Normo-glycaemia	6 (0.8)	7	0.8	1 (0.3)	1	0.2
Pre-diabetes	7 (1.2)	8	1.0	1 (0.4)	1	0.3
Lipase increased						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2
Pre-diabetes	7 (1.2)	7	0.9	1 (0.4)	1	0.3
Amylase increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gastric pH						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pancreatic enzymes increased						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Protein and chemistry analyses NEC						
Normo-glycaemia	6 (0.8)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	7 (1.2)	7	0.9	3 (1.1)	3	0.9
C-reactive protein increased						
Normo-glycaemia	6 (0.8)	6	0.6	2 (0.5)	2	0.4
Pre-diabetes	7 (1.2)	7	0.9	3 (1.1)	3	0.9
Cardiac and vascular investigations (excl enzyme tests)						
Normo-glycaemia	4 (0.6)	6	0.6	4 (1.0)	4	0.8
Pre-diabetes	6 (1.0)	6	0.8	3 (1.1)	3	0.9
Heart rate increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
QRS axis abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Blood pressure abnormal						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Cardiac murmur						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Electrocardiogram ST segment depression						
Normo-glycaemia	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Electrocardiogram T wave inversion						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Blood pressure decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Blood pressure increased						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	0			3 (1.1)	3	0.9
Electrocardiogram T wave amplitude decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pulse abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Electrocardiogram T wave abnormal						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Lipid analyses						
Normo-glycaemia	4 (0.6)	8	0.9	0		
Pre-diabetes	5 (0.8)	8	1.0	4 (1.5)	5	1.5
High density lipoprotein decreased						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Blood cholesterol increased						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Low density lipoprotein increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Lipids increased						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Blood triglycerides increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Very low density lipoprotein increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Endocrine investigations (incl sex hormones)						
Normo-glycaemia	3 (0.4)	5	0.5	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	5	0.6	0		
Blood calcitonin increased						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Blood thyroid stimulating hormone decreased						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Blood thyroid stimulating hormone abnormal						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Thyroxine free increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Thyroxine increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Blood thyroid stimulating hormone increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Physical examination and organ system status topics						
Normo-glycaemia	5 (0.7)	5	0.5	2 (0.5)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Weight decreased						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	0			0		
Weight increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Body mass index decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Respiratory rate increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Body temperature increased						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	0			0		
Enzyme investigations NEC						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	5 (1.9)	5	1.5
Blood creatine phosphokinase increased						
Normo-glycaemia	4 (0.6)	4	0.4	3 (0.8)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	4 (1.5)	4	1.2
Enzyme level increased						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Blood alkaline phosphatase increased						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Microbiology and serology investigations						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
HIV test positive						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Helicobacter test positive						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Human papilloma virus test positive						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Renal and urinary tract investigations and urinalyses						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Blood creatinine increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
White blood cells urine						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Glomerular filtration rate decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			2 (0.8)	2	0.6
Blood urine present						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Haematology investigations (incl blood groups)						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	4	0.8
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Haemoglobin decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Haematology test abnormal						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Haematocrit increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Haemoglobin increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Red blood cell count increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Red cell distribution width increased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Metabolic, nutritional and blood gas investigations						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	4 (1.5)	4	1.2
Blood glucose increased						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Blood uric acid increased						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Glycosylated haemoglobin increased						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Vitamin D decreased						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Reproductive organ and breast investigations (excl hormone analyses)						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Biopsy breast						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Cytogenetic investigations						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Prostatic specific antigen increased						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Investigations, imaging and histopathology procedures NEC						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Smear test						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Precancerous cells present						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Endoscopy						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Water, electrolyte and mineral investigations						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	0			2 (0.8)	2	0.6
Blood calcium decreased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Blood potassium increased						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Blood iron decreased						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Blood sodium increased						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Serum ferritin decreased						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Musculoskeletal and soft tissue investigations (excl enzyme tests)						
Normo-glycaemia	1 (0.1)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Arthroscopy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Immunology and allergy investigations						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Antinuclear antibody positive						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Vascular disorders						
Normo-glycaemia	40 (5.6)	41	4.4	24 (6.1)	25	5.0
Pre-diabetes	50 (8.4)	56	7.2	21 (8.0)	25	7.5
Vascular hypertensive disorders						
Normo-glycaemia	19 (2.7)	19	2.0	14 (3.6)	15	3.0
Pre-diabetes	23 (3.9)	23	3.0	14 (5.3)	17	5.1
Hypertension						
Normo-glycaemia	19 (2.7)	19	2.0	14 (3.6)	15	3.0
Pre-diabetes	21 (3.5)	21	2.7	13 (4.9)	16	4.8
Essential hypertension						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypertensive emergency						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypertensive crisis						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Decreased and nonspecific blood pressure disorders and shock						
Normo-glycaemia	7 (1.0)	8	0.9	0		
Pre-diabetes	12 (2.0)	13	1.7	2 (0.8)	2	0.6
Hypotension						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	7 (1.2)	8	1.0	2 (0.8)	2	0.6
Orthostatic hypotension						
Normo-glycaemia	4 (0.6)	5	0.5	0		
Pre-diabetes	4 (0.7)	4	0.5	0		
Circulatory collapse						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Vascular disorders NEC						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	6 (1.0)	7	0.9	1 (0.4)	1	0.3
Hot flush						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	5	0.6	0		
Flushing						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Arteriosclerosis, stenosis, vascular insufficiency and necrosis						
Normo-glycaemia	4 (0.6)	4	0.4	4 (1.0)	4	0.8

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	3 (0.5)	3	0.4	0		
Peripheral venous disease						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Peripheral coldness						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Arteriosclerosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Aortic arteriosclerosis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Raynaud's phenomenon						
Normo-glycaemia	0			3 (0.8)	3	0.6
Pre-diabetes	0			0		
Venous varices						
Normo-glycaemia	0			0		
Pre-diabetes	6 (1.0)	6	0.8	0		
Varicose vein						
Normo-glycaemia	0			0		
Pre-diabetes	6 (1.0)	6	0.8	0		
Vascular haemorrhagic disorders						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	3 (1.1)	3	0.9
Haematoma						
Normo-glycaemia	4 (0.6)	4	0.4	1 (0.3)	1	0.2

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (0.3)	2	0.3	3 (1.1)	3	0.9
Embolism and thrombosis						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Thrombosis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Thrombophlebitis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Deep vein thrombosis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Thrombophlebitis superficial						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Vascular infections and inflammations						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Phlebitis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Arteritis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Lymphatic vessel disorders						
Normo-glycaemia	0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0		
Lymphoedema						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Cardiac disorders						
Normo-glycaemia	27 (3.8)	28	3.0	18 (4.6)	23	4.6
Pre-diabetes	27 (4.6)	34	4.4	15 (5.7)	21	6.3
Cardiac arrhythmias						
Normo-glycaemia	13 (1.8)	14	1.5	10 (2.6)	12	2.4
Pre-diabetes	19 (3.2)	24	3.1	7 (2.7)	9	2.7
Atrial fibrillation						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	7	0.9	2 (0.8)	3	0.9
Tachycardia						
Normo-glycaemia	1 (0.1)	1	0.1	3 (0.8)	3	0.6
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	2	0.6
Atrioventricular block first degree						
Normo-glycaemia	3 (0.4)	3	0.3	4 (1.0)	4	0.8
Pre-diabetes	2 (0.3)	2	0.3	0		
Bundle branch block left						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Arrhythmia						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Ventricular extrasystoles						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Sinus tachycardia						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Atrial flutter						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Atrioventricular block						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Atrioventricular block second degree						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Bundle branch block right						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Cardiac flutter						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Defect conduction intraventricular						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Nodal rhythm						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Atrial tachycardia						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bradycardia						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	0			1 (0.4)	1	0.3
Sinus bradycardia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Supraventricular extrasystoles						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Cardiac disorders, signs and symptoms NEC						
Normo-glycaemia	6 (0.8)	6	0.6	6 (1.5)	8	1.6
Pre-diabetes	6 (1.0)	6	0.8	2 (0.8)	2	0.6
Palpitations						
Normo-glycaemia	5 (0.7)	5	0.5	5 (1.3)	7	1.4
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	1	0.3
Cardiovascular disorder						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypertensive heart disease						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Coronary artery disorders						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	3 (0.5)	3	0.4	5 (1.9)	6	1.8

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Angina pectoris						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Acute myocardial infarction						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Coronary artery stenosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Angina unstable						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Arteriosclerosis coronary artery						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Coronary artery disease						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Myocardial infarction						
Normo-glycaemia	0			0		
Pre-diabetes	0			2 (0.8)	2	0.6
Cardiac valve disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	2	0.6
Aortic valve incompetence						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Aortic valve sclerosis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Mitral valve incompetence						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Tricuspid valve incompetence						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Myocardial disorders						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Left ventricular hypertrophy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Cardiomegaly						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Cardiomyopathy						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Myocarditis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Cardiac neoplasms						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pericardial cyst						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pericardial disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pericardial disease						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Normo-glycaemia	25 (3.5)	29	3.1	15 (3.8)	15	3.0
Pre-diabetes	21 (3.5)	23	3.0	10 (3.8)	12	3.6
Cutaneous neoplasms benign						
Normo-glycaemia	7 (1.0)	9	1.0	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	5	0.6	5 (1.9)	5	1.5
Melanocytic naevus						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	3 (0.5)	4	0.5	2 (0.8)	2	0.6
Acrochordon						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Seborrhoeic keratosis						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			1 (0.4)	1	0.3
Dysplastic naevus						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Skin papilloma						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Pyogenic granuloma						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Reproductive neoplasms female benign						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Uterine leiomyoma						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Ovarian adenoma						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Soft tissue neoplasms benign						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Lipoma						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Leiomyoma						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Breast neoplasms malignant and unspecified (incl nipple)						
Normo-glycaemia	2 (0.3)	2	0.2	3 (0.8)	3	0.6
Pre-diabetes	2 (0.3)	2	0.3	0		
Intraductal proliferative breast lesion						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Invasive ductal breast carcinoma						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Breast cancer						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Lobular breast carcinoma in situ						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Phyllodes tumour						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Skin neoplasms malignant and unspecified						
Normo-glycaemia	3 (0.4)	3	0.3	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Basal cell carcinoma						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Malignant melanoma						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Malignant melanoma in situ						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Neoplasm skin						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Gastrointestinal neoplasms benign						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Colon adenoma						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Breast neoplasms benign (incl nipple)						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Benign breast neoplasm						
Normo-glycaemia	1 (0.1)	1	0.1	2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Miscellaneous and site unspecified neoplasms malignant and unspecified						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Squamous cell carcinoma						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Neoplasm						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Endocrine neoplasms benign						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Benign neoplasm of thyroid gland						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Parathyroid tumour benign						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Hepatic and biliary neoplasms benign						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Haemangioma of liver						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Endocrine neoplasms malignant and unspecified						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Papillary thyroid cancer						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Gastrointestinal neoplasms malignant and unspecified						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gastrointestinal stromal tumour						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hepatobiliary neoplasms malignant and unspecified						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hepatic neoplasm						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Miscellaneous and site unspecified neoplasms benign						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Fibroma						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Adenoma benign						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Reproductive neoplasms male malignant and unspecified						
Normo-glycaemia	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Prostate cancer						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Skeletal neoplasms benign						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Haemangioma of bone						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Soft tissue neoplasms malignant and unspecified						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Dermatofibrosarcoma protuberans						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Reproductive neoplasms female malignant and unspecified						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Cervix carcinoma stage 0						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Leukaemias						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Hairy cell leukaemia						
Normo-glycaemia	0			1	(0.3)	1 0.2
Pre-diabetes	0			0		
Nervous system neoplasms malignant and unspecified NEC						
Normo-glycaemia	0			1	(0.3)	1 0.2
Pre-diabetes	0			0		
Glioblastoma						
Normo-glycaemia	0			1	(0.3)	1 0.2
Pre-diabetes	0			0		
Ocular neoplasms						
Normo-glycaemia	0			1	(0.3)	1 0.2
Pre-diabetes	0			0		
Eyelid haemangioma						
Normo-glycaemia	0			1	(0.3)	1 0.2
Pre-diabetes	0			0		
Plasma cell neoplasms						
Normo-glycaemia	0			0		
Pre-diabetes	0			1	(0.4)	1 0.3
Paraproteinaemia						
Normo-glycaemia	0			0		
Pre-diabetes	0			1	(0.4)	1 0.3
Renal and urinary tract neoplasms benign						
Normo-glycaemia	0			0		
Pre-diabetes	0			1	(0.4)	1 0.3
Kidney angiomyolipoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Renal and urinary tract neoplasms malignant and unspecified						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Urinary tract neoplasm						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Ear and labyrinth disorders						
Normo-glycaemia	26 (3.6)	33	3.5	14 (3.6)	17	3.4
Pre-diabetes	19 (3.2)	23	3.0	10 (3.8)	12	3.6
Inner ear and VIIIth cranial nerve disorders						
Normo-glycaemia	13 (1.8)	15	1.6	11 (2.8)	14	2.8
Pre-diabetes	9 (1.5)	11	1.4	7 (2.7)	8	2.4
Vertigo						
Normo-glycaemia	10 (1.4)	10	1.1	9 (2.3)	10	2.0
Pre-diabetes	7 (1.2)	7	0.9	3 (1.1)	3	0.9
Tinnitus						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	2	0.4
Pre-diabetes	2 (0.3)	3	0.4	1 (0.4)	1	0.3
Vertigo positional						
Normo-glycaemia	2 (0.3)	3	0.3	0		
Pre-diabetes	1 (0.2)	1	0.1	3 (1.1)	4	1.2
Meniere's disease						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Motion sickness						
Normo-glycaemia	0			1 (0.3)	2	0.4
Pre-diabetes	0			0		
Aural disorders NEC						
Normo-glycaemia	9 (1.3)	10	1.1	1 (0.3)	1	0.2
Pre-diabetes	6 (1.0)	6	0.8	1 (0.4)	1	0.3
Ear pain						
Normo-glycaemia	7 (1.0)	8	0.9	1 (0.3)	1	0.2
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	1	0.3
Ear discomfort						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Ear congestion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Middle ear disorders (excl congenital)						
Normo-glycaemia	4 (0.6)	4	0.4	2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	3	0.4	0		
Eustachian tube dysfunction						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	2	0.3	0		
Eustachian tube disorder						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Tympanic membrane disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Hearing disorders						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	1 (0.2)	1	0.1	2 (0.8)	2	0.6
Deafness neurosensory						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Sudden hearing loss						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypoacusis						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Deafness						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hyperacusis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
External ear disorders (excl congenital)						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Cerumen impaction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Excessive cerumen production						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hepatobiliary disorders						
Normo-glycaemia	22 (3.1)	28	3.0	7 (1.8)	7	1.4
Pre-diabetes	22 (3.7)	28	3.6	6 (2.3)	7	2.1
Gallbladder disorders						
Normo-glycaemia	16 (2.2)	19	2.0	3 (0.8)	3	0.6
Pre-diabetes	15 (2.5)	19	2.5	2 (0.8)	2	0.6
Cholelithiasis						
Normo-glycaemia	12 (1.7)	12	1.3	2 (0.5)	2	0.4
Pre-diabetes	11 (1.9)	12	1.5	2 (0.8)	2	0.6
Cholecystitis acute						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	3 (0.5)	3	0.4	0		
Cholecystitis						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Gallbladder disorder						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Cholecystitis chronic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Biliary dyskinesia						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Hepatic and hepatobiliary disorders						
Normo-glycaemia	5 (0.7)	7	0.8	4 (1.0)	4	0.8
Pre-diabetes	8 (1.3)	9	1.2	5 (1.9)	5	1.5
Hepatic steatosis						
Normo-glycaemia	1 (0.1)	1	0.1	4 (1.0)	4	0.8
Pre-diabetes	5 (0.8)	5	0.6	3 (1.1)	3	0.9
Hepatic cyst						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Hepatic function abnormal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Granulomatous liver disease						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hepatic pain						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypertransaminasaemia						
Normo-glycaemia	1 (0.1)	3	0.3	0		
Pre-diabetes	0			0		
Nonalcoholic fatty liver disease						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Portal vein thrombosis						
Normo-glycaemia	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Bile duct disorders						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Bile duct stone						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Biliary colic						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Eye disorders						
Normo-glycaemia	23 (3.2)	28	3.0	13 (3.3)	14	2.8
Pre-diabetes	21 (3.5)	30	3.9	11 (4.2)	17	5.1
Vision disorders						
Normo-glycaemia	9 (1.3)	9	1.0	2 (0.5)	2	0.4
Pre-diabetes	5 (0.8)	8	1.0	2 (0.8)	2	0.6
Vision blurred						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Myopia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Diplopia						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	2	0.3	0		
Astigmatism						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Anisometropia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Photopsia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Visual impairment						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Scintillating scotoma						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Eye disorders NEC						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	6 (1.0)	6	0.8	4 (1.5)	4	1.2
Dry eye						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	3 (0.5)	3	0.4	3 (1.1)	3	0.9
Eyelid disorder						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Eye pain						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Lacrimation increased						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Ocular discomfort						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Ocular infections, irritations and inflammations						
Normo-glycaemia	3 (0.4)	4	0.4	3 (0.8)	3	0.6
Pre-diabetes	5 (0.8)	6	0.8	4 (1.5)	7	2.1
Eye pruritus						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Conjunctivitis allergic						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Eczema eyelids						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Eye allergy						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Eye discharge						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Ocular hyperaemia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Conjunctival irritation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Meibomian gland dysfunction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Swelling of eyelid						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Blepharitis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Conjunctival hyperaemia						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Erythema of eyelid						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Eye inflammation						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	2	0.6
Eye irritation						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Keratitis						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Ulcerative keratitis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Anterior eye structural change, deposit and degeneration						
Normo-glycaemia	3 (0.4)	3	0.3	3 (0.8)	4	0.8
Pre-diabetes	4 (0.7)	5	0.6	0		
Cataract						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	2	0.4
Pre-diabetes	3 (0.5)	4	0.5	0		
Xerophthalmia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Ectropion						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Pterygium						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Glaucoma and ocular hypertension						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	0			1 (0.4)	2	0.6
Glaucoma						
Normo-glycaemia	4 (0.6)	4	0.4	0		
Pre-diabetes	0			1 (0.4)	2	0.6
Ocular structural change, deposit and degeneration NEC						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	3	0.4	1 (0.4)	1	0.3
Macular degeneration						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	3	0.4	0		
Vitreous detachment						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Ocular haemorrhages and vascular disorders NEC						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Optic ischaemic neuropathy						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Eyelid haematoma						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Conjunctival haemorrhage						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Retina, choroid and vitreous haemorrhages and vascular disorders						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	1 (0.4)	1	0.3
Retinopathy						
Normo-glycaemia	0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (0.3)	2	0.3	0		
Retinal aneurysm						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Ocular neuromuscular disorders						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Blepharospasm						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Ocular sensory symptoms NEC						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Asthenopia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Renal and urinary disorders						
Normo-glycaemia	16 (2.2)	17	1.8	12 (3.1)	13	2.6
Pre-diabetes	25 (4.2)	34	4.4	10 (3.8)	11	3.3
Urinary tract signs and symptoms						
Normo-glycaemia	13 (1.8)	14	1.5	6 (1.5)	7	1.4
Pre-diabetes	13 (2.2)	15	1.9	2 (0.8)	2	0.6
Dysuria						
Normo-glycaemia	4 (0.6)	5	0.5	0		
Pre-diabetes	5 (0.8)	6	0.8	0		
Haematuria						

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normo-glycaemia	3	(0.4)	3	0.3	1	(0.3)	1	0.2
Pre-diabetes	0				0			
Pollakiuria								
Normo-glycaemia	0				0			
Pre-diabetes	2	(0.3)	2	0.3	1	(0.4)	1	0.3
Stress urinary incontinence								
Normo-glycaemia	0				0			
Pre-diabetes	2	(0.3)	2	0.3	0			
Chromaturia								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Renal pain								
Normo-glycaemia	2	(0.3)	2	0.2	0			
Pre-diabetes	0				0			
Nocturia								
Normo-glycaemia	0				2	(0.5)	2	0.4
Pre-diabetes	1	(0.2)	1	0.1	0			
Renal colic								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	2	0.3	0			
Urine odour abnormal								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	1	(0.4)	1	0.3
Bladder pain								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Micturition urgency								

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Normo-glycaemia	1	(0.1)	1	0.1	1	(0.3)	1	0.2
Pre-diabetes	0				0			
Urine flow decreased								
Normo-glycaemia	1	(0.1)	1	0.1	0			
Pre-diabetes	0				0			
Polyuria								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Urinary incontinence								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Urinary retention								
Normo-glycaemia	0				1	(0.3)	1	0.2
Pre-diabetes	0				0			
Urolithiases								
Normo-glycaemia	2	(0.3)	2	0.2	4	(1.0)	4	0.8
Pre-diabetes	9	(1.5)	10	1.3	2	(0.8)	2	0.6
Nephrolithiasis								
Normo-glycaemia	2	(0.3)	2	0.2	4	(1.0)	4	0.8
Pre-diabetes	6	(1.0)	6	0.8	2	(0.8)	2	0.6
Calculus urinary								
Normo-glycaemia	0				0			
Pre-diabetes	3	(0.5)	3	0.4	0			
Ureterolithiasis								
Normo-glycaemia	0				0			
Pre-diabetes	1	(0.2)	1	0.1	0			
Renal disorders (excl nephropathies)								

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	7 (1.2)	9	1.2	5 (1.9)	6	1.8
Acute kidney injury						
Normo-glycaemia	0			0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	1	0.3
Renal cyst						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	2 (0.3)	2	0.3	2 (0.8)	2	0.6
Chronic kidney disease						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Hydronephrosis						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Nephrectasia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Renal impairment						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Hypertensive nephropathy						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Bladder and bladder neck disorders (excl calculi)						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cystitis noninfective						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Urethral disorders (excl calculi)						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Urethritis noninfective						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Blood and lymphatic system disorders						
Normo-glycaemia	13 (1.8)	13	1.4	8 (2.0)	12	2.4
Pre-diabetes	22 (3.7)	24	3.1	8 (3.0)	9	2.7
Anaemias nonhaemolytic and marrow depression						
Normo-glycaemia	8 (1.1)	8	0.9	4 (1.0)	5	1.0
Pre-diabetes	16 (2.7)	17	2.2	6 (2.3)	6	1.8
Anaemia						
Normo-glycaemia	8 (1.1)	8	0.9	3 (0.8)	4	0.8
Pre-diabetes	11 (1.9)	12	1.5	6 (2.3)	6	1.8
Iron deficiency anaemia						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Blood loss anaemia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Hypochromic anaemia						

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pernicious anaemia						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Pancytopenia						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Spleen, lymphatic and reticuloendothelial system disorders						
Normo-glycaemia	2 (0.3)	2	0.2	2 (0.5)	2	0.4
Pre-diabetes	5 (0.8)	5	0.6	1 (0.4)	2	0.6
Lymphadenopathy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	3 (0.5)	3	0.4	1 (0.4)	2	0.6
Hypersplenism						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Splenomegaly						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	1 (0.2)	1	0.1	0		
Splenic haemorrhage						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
White blood cell disorders						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Leukocytosis						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Eosinophilia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Platelet disorders						
Normo-glycaemia	0			3 (0.8)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Thrombocytopenia						
Normo-glycaemia	0			3 (0.8)	3	0.6
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Red blood cell disorders						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Polycythaemia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Microcytosis						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Immune system disorders						
Normo-glycaemia	16 (2.2)	16	1.7	13 (3.3)	14	2.8
Pre-diabetes	12 (2.0)	12	1.5	8 (3.0)	9	2.7
Allergic conditions						
Normo-glycaemia	15 (2.1)	15	1.6	13 (3.3)	14	2.8

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	12 (2.0)	12	1.5	8 (3.0)	9	2.7
Seasonal allergy						
Normo-glycaemia	9 (1.3)	9	1.0	8 (2.0)	8	1.6
Pre-diabetes	6 (1.0)	6	0.8	6 (2.3)	6	1.8
Allergy to arthropod bite						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Hypersensitivity						
Normo-glycaemia	2 (0.3)	2	0.2	5 (1.3)	5	1.0
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Drug hypersensitivity						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	2 (0.3)	2	0.3	0		
Food allergy						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Allergy to arthropod sting						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Rubber sensitivity						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Mite allergy						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Multiple allergies						
Normo-glycaemia	0			0		

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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Immune disorders NEC						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Immunisation reaction						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Surgical and medical procedures						
Normo-glycaemia	12 (1.7)	13	1.4	6 (1.5)	6	1.2
Pre-diabetes	6 (1.0)	6	0.8	2 (0.8)	2	0.6
Head and neck therapeutic procedures						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	4 (0.7)	4	0.5	0		
Tooth extraction						
Normo-glycaemia	0			0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Dental operation						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Dental implantation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Sinus operation						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Therapeutic procedures and supportive care NEC						
Normo-glycaemia	3 (0.4)	3	0.3	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Polypectomy						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Cyst removal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Spinal anaesthesia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Skin and subcutaneous tissue therapeutic procedures						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Acrochordon excision						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Skin neoplasm excision						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Nervous system, skull and spine therapeutic procedures						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Intervertebral disc operation						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Bone and joint therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Synovial cyst removal						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bone prosthesis insertion						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hip surgery						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Eye therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Glaucoma surgery						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Gastrointestinal therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			1 (0.4)	1	0.3
Gastric bypass						
Normo-glycaemia	1 (0.1)	1	0.1	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (0.4)	1	0.3
Abdominoplasty						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Hepatobiliary therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Cholecystectomy						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Obstetric and gynaecological therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	0			0		
Abortion induced						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Ovarian operation						
Normo-glycaemia	0			1 (0.3)	1	0.2
Pre-diabetes	0			0		
Soft tissue therapeutic procedures						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Lipoma excision						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Endocrine disorders						
Normo-glycaemia	7 (1.0)	8	0.9	3 (0.8)	3	0.6
Pre-diabetes	7 (1.2)	8	1.0	3 (1.1)	4	1.2
Thyroid gland disorders						
Normo-glycaemia	6 (0.8)	7	0.8	3 (0.8)	3	0.6
Pre-diabetes	7 (1.2)	8	1.0	3 (1.1)	3	0.9
Hypothyroidism						
Normo-glycaemia	0			2 (0.5)	2	0.4
Pre-diabetes	4 (0.7)	4	0.5	2 (0.8)	2	0.6
Goitre						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Thyroid mass						
Normo-glycaemia	2 (0.3)	2	0.2	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Hyperthyroidism						
Normo-glycaemia	3 (0.4)	4	0.4	0		
Pre-diabetes	0			0		
Thyroid cyst						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Primary hyperthyroidism						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Adrenal gland disorders						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hyperadrenocorticism						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Endocrine disorders of gonadal function						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Hypogonadism						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Social circumstances						
Normo-glycaemia	5 (0.7)	5	0.5	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Economic and housing issues						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Stress at work						
Normo-glycaemia	1 (0.1)	1	0.1	1 (0.3)	1	0.2
Pre-diabetes	1 (0.2)	1	0.1	0		
Age related factors						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Menopause						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Family issues						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Family stress						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Lifestyle issues						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Bedridden						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Pregnancy, puerperium and perinatal conditions						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	2 (0.3)	2	0.3	0		
Abortions and stillbirth						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Abortion spontaneous						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	0			0		
Abortion						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Maternal complications of pregnancy						
Normo-glycaemia	1 (0.1)	1	0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (0.2)	1	0.1	0		
Morning sickness						
Normo-glycaemia	0			0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Ectopic pregnancy						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Congenital, familial and genetic disorders						
Normo-glycaemia	3 (0.4)	3	0.3	0		
Pre-diabetes	1 (0.2)	1	0.1	1 (0.4)	1	0.3
Metabolic and nutritional disorders congenital						
Normo-glycaemia	2 (0.3)	2	0.2	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Type V hyperlipidaemia						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	1 (0.2)	1	0.1	0		
Gilbert's syndrome						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Musculoskeletal and connective tissue disorders congenital						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Carpus curvus						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Skin and subcutaneous tissue disorders congenital						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Dermoid cyst						
Normo-glycaemia	0			0		
Pre-diabetes	0			1 (0.4)	1	0.3
Product issues						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Device issues						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		
Device expulsion						
Normo-glycaemia	1 (0.1)	1	0.1	0		
Pre-diabetes	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

45 Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Normo-glycaemia	55		74.1		106		145.7		51		71.3	
Pre-diabetes	20		26.6		44		61.1		25		34.9	
T2D	25		35.5		49		68.3		25		35.6	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Normo-glycaemia	45	(81.8)	203	274.0	93	(87.7)	430	295.2	40	(78.4)	138	193.5
Pre-diabetes	15	(75.0)	192	722.4	40	(90.9)	156	255.4	20	(80.0)	45	129.0
T2D	22	(88.0)	88	247.6	38	(77.6)	248	363.3	20	(80.0)	52	146.0
Serious												
Yes												
Normo-glycaemia	5	(9.1)	5	6.7	7	(6.6)	9	6.2	4	(7.8)	4	5.6
Pre-diabetes	2	(10.0)	5	18.8	1	(2.3)	1	1.6	1	(4.0)	1	2.9
T2D	0				2	(4.1)	2	2.9	2	(8.0)	2	5.6
No												
Normo-glycaemia	45	(81.8)	198	267.2	92	(86.8)	421	289.0	38	(74.5)	134	187.9
Pre-diabetes	15	(75.0)	187	703.6	40	(90.9)	155	253.8	20	(80.0)	44	126.1
T2D	22	(88.0)	88	247.6	38	(77.6)	246	360.4	20	(80.0)	50	140.4
Severity												
Severe												
Normo-glycaemia	2	(3.6)	2	2.7	3	(2.8)	4	2.7	5	(9.8)	5	7.0
Pre-diabetes	1	(5.0)	1	3.8	0				0			
T2D	0				0				0			

Adverse events with onset prior to randomisation are not included.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Severity									
Moderate									
Normo-glycaemia	8 (14.5)	22	29.7	14 (13.2)	27	18.5	5 (9.8)	7	9.8
Pre-diabetes	2 (10.0)	36	135.5	4 (9.1)	7	11.5	2 (8.0)	2	5.7
T2D	4 (16.0)	5	14.1	7 (14.3)	8	11.7	4 (16.0)	4	11.2
Mild									
Normo-glycaemia	44 (80.0)	179	241.6	90 (84.9)	399	273.9	36 (70.6)	126	176.7
Pre-diabetes	14 (70.0)	155	583.2	40 (90.9)	149	244.0	20 (80.0)	43	123.3
T2D	21 (84.0)	83	233.6	38 (77.6)	240	351.6	20 (80.0)	48	134.7
Relationship to trial product									
Missing									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Probable									
Normo-glycaemia	12 (21.8)	22	29.7	28 (26.4)	72	49.4	7 (13.7)	11	15.4
Pre-diabetes	8 (40.0)	33	124.2	10 (22.7)	26	42.6	1 (4.0)	2	5.7
T2D	5 (20.0)	6	16.9	17 (34.7)	60	87.9	2 (8.0)	3	8.4
Possible									
Normo-glycaemia	32 (58.2)	61	82.3	50 (47.2)	129	88.5	6 (11.8)	9	12.6
Pre-diabetes	10 (50.0)	109	410.1	9 (20.5)	25	40.9	2 (8.0)	2	5.7
T2D	13 (52.0)	20	56.3	25 (51.0)	52	76.2	2 (8.0)	6	16.8
Unlikely									
Normo-glycaemia	39 (70.9)	120	161.9	81 (76.4)	229	157.2	37 (72.5)	118	165.4
Pre-diabetes	13 (65.0)	50	188.1	37 (84.1)	104	170.3	19 (76.0)	41	117.5
T2D	21 (84.0)	62	174.5	34 (69.4)	136	199.2	18 (72.0)	43	120.7

Adverse events with onset prior to randomisation are not included.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by glycaemic status at baseline - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Outcome									
Recovered									
Normo-glycaemia	44 (80.0)	165	222.7	89 (84.0)	377	258.8	40 (78.4)	114	159.8
Pre-diabetes	14 (70.0)	179	673.5	38 (86.4)	131	214.5	17 (68.0)	34	97.5
T2D	20 (80.0)	65	182.9	37 (75.5)	221	323.7	18 (72.0)	38	106.7
Recovering									
Normo-glycaemia	3 (5.5)	6	8.1	6 (5.7)	8	5.5	2 (3.9)	2	2.8
Pre-diabetes	2 (10.0)	3	11.3	3 (6.8)	4	6.5	1 (4.0)	1	2.9
T2D	4 (16.0)	7	19.7	7 (14.3)	9	13.2	2 (8.0)	2	5.6
Not Recovered									
Normo-glycaemia	16 (29.1)	32	43.2	29 (27.4)	45	30.9	12 (23.5)	22	30.8
Pre-diabetes	6 (30.0)	10	37.6	13 (29.5)	21	34.4	7 (28.0)	10	28.7
T2D	13 (52.0)	16	45.0	12 (24.5)	18	26.4	7 (28.0)	12	33.7
Leading to									
Permanent treatment discontinuation									
Normo-glycaemia	2 (3.6)	5	6.7	4 (3.8)	6	4.1	0		
Pre-diabetes	1 (5.0)	1	3.8	0			1 (4.0)	1	2.9
T2D	0			1 (2.0)	3	4.4	0		
Temporary interruption of trial product									
Normo-glycaemia	5 (9.1)	7	9.4	9 (8.5)	21	14.4	4 (7.8)	4	5.6
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	1 (4.0)	1	2.8	5 (10.2)	5	7.3	1 (4.0)	1	2.8
Dose reduction of trial product									
Normo-glycaemia	1 (1.8)	1	1.3	9 (8.5)	12	8.2	0		
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	0			5 (10.2)	7	10.3	0		

Adverse events with onset prior to randomisation are not included.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

46 Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Normo-glycaemia	55	74.1			106	145.7			51	71.3		
Pre-diabetes	20	26.6			44	61.1			25	34.9		
T2D	25	35.5			49	68.3			25	35.6		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Normo-glycaemia	45	(81.8)	203	274.0	93	(87.7)	430	295.2	40	(78.4)	138	193.5
Pre-diabetes	15	(75.0)	192	722.4	40	(90.9)	156	255.4	20	(80.0)	45	129.0
T2D	22	(88.0)	88	247.6	38	(77.6)	248	363.3	20	(80.0)	52	146.0
Gastrointestinal disorders												
Normo-glycaemia	35	(63.6)	89	120.1	61	(57.5)	185	127.0	18	(35.3)	29	40.7
Pre-diabetes	14	(70.0)	138	519.3	25	(56.8)	66	108.1	5	(20.0)	6	17.2
T2D	15	(60.0)	29	81.6	32	(65.3)	92	134.8	7	(28.0)	8	22.5
Gastrointestinal motility and defaecation conditions												
Normo-glycaemia	22	(40.0)	28	37.8	39	(36.8)	56	38.4	5	(9.8)	5	7.0
Pre-diabetes	10	(50.0)	43	161.8	16	(36.4)	25	40.9	2	(8.0)	2	5.7
T2D	9	(36.0)	13	36.6	23	(46.9)	38	55.7	2	(8.0)	2	5.6
Constipation												
Normo-glycaemia	10	(18.2)	11	14.8	24	(22.6)	31	21.3	3	(5.9)	3	4.2
Pre-diabetes	6	(30.0)	7	26.3	11	(25.0)	11	18.0	0			
T2D	3	(12.0)	4	11.3	17	(34.7)	18	26.4	0			
Diarrhoea												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	12 (21.8)	16	21.6	17 (16.0)	22	15.1	2 (3.9)	2	2.8
Pre-diabetes	5 (25.0)	36	135.5	6 (13.6)	11	18.0	2 (8.0)	2	5.7
T2D	5 (20.0)	7	19.7	9 (18.4)	19	27.8	2 (8.0)	2	5.6
Gastrooesophageal reflux disease									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			3 (6.8)	3	4.9	0		
T2D	2 (8.0)	2	5.6	1 (2.0)	1	1.5	0		
Gastrointestinal motility disorder									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Irritable bowel syndrome									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Gastrointestinal signs and symptoms									
Normo-glycaemia	24 (43.6)	50	67.5	45 (42.5)	109	74.8	9 (17.6)	14	19.6
Pre-diabetes	8 (40.0)	90	338.6	7 (15.9)	19	31.1	1 (4.0)	2	5.7
T2D	7 (28.0)	11	31.0	19 (38.8)	41	60.1	1 (4.0)	1	2.8
Nausea									
Normo-glycaemia	9 (16.4)	15	20.2	21 (19.8)	40	27.5	3 (5.9)	3	4.2
Pre-diabetes	4 (20.0)	7	26.3	3 (6.8)	8	13.1	1 (4.0)	1	2.9
T2D	5 (20.0)	5	14.1	11 (22.4)	18	26.4	0		
Vomiting									
Normo-glycaemia	6 (10.9)	6	8.1	12 (11.3)	20	13.7	0		
Pre-diabetes	3 (15.0)	27	101.6	1 (2.3)	1	1.6	1 (4.0)	1	2.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	1	2.8	4 (8.2)	8	11.7	1 (4.0)	1	2.8
Abdominal pain									
Normo-glycaemia	3 (5.5)	4	5.4	8 (7.5)	11	7.6	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			3 (6.1)	4	5.9	0		
Abdominal discomfort									
Normo-glycaemia	9 (16.4)	10	13.5	9 (8.5)	12	8.2	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	1 (4.0)	1	2.8	3 (6.1)	4	5.9	0		
Abdominal pain upper									
Normo-glycaemia	1 (1.8)	1	1.3	6 (5.7)	9	6.2	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	2	7.5	2 (4.5)	2	3.3	0		
T2D	1 (4.0)	2	5.6	2 (4.1)	2	2.9	0		
Dyspepsia									
Normo-glycaemia	4 (7.3)	4	5.4	5 (4.7)	6	4.1	1 (2.0)	4	5.6
Pre-diabetes	2 (10.0)	13	48.9	3 (6.8)	7	11.5	0		
T2D	0			1 (2.0)	1	1.5	0		
Abdominal distension									
Normo-glycaemia	4 (7.3)	5	6.7	5 (4.7)	5	3.4	2 (3.9)	3	4.2
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	1 (4.0)	1	2.8	2 (4.1)	3	4.4	0		
Abdominal tenderness									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Eructation									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	2 (3.6)	2	2.7	2 (1.9)	2	1.4	0		
Pre-diabetes	2 (10.0)	19	71.5	0			0		
T2D	0			0			0		
Faeces soft									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Faeces hard									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Flatulence									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	1 (5.0)	18	67.7	0			0		
T2D	0			0			0		
Abdominal pain lower									
Normo-glycaemia	1 (1.8)	2	2.7	0			1 (2.0)	2	2.8
Pre-diabetes	0			0			0		
T2D	0			0			0		
Epigastric discomfort									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Dental and gingival conditions									
Normo-glycaemia	3 (5.5)	3	4.0	5 (4.7)	5	3.4	2 (3.9)	2	2.8
Pre-diabetes	2 (10.0)	2	7.5	5 (11.4)	6	9.8	2 (8.0)	2	5.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	1	2.8	4 (8.2)	4	5.9	2 (8.0)	2	5.6
Dental caries									
Normo-glycaemia	2 (3.6)	2	2.7	4 (3.8)	4	2.7	2 (3.9)	2	2.8
Pre-diabetes	2 (10.0)	2	7.5	4 (9.1)	5	8.2	1 (4.0)	1	2.9
T2D	0			3 (6.1)	3	4.4	2 (8.0)	2	5.6
Toothache									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Tooth impacted									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Dental cyst									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Gastrointestinal conditions NEC									
Normo-glycaemia	1 (1.8)	1	1.3	4 (3.8)	5	3.4	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	4 (9.1)	4	6.5	0		
T2D	2 (8.0)	2	5.6	2 (4.1)	3	4.4	0		
Gastric disorder									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Food poisoning									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	0			0			0		
Gastrointestinal disorder									
Normo-glycaemia	0			3 (2.8)	4	2.7	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	2	2.9	0		
Barrett's oesophagus									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Gastrointestinal inflammatory conditions									
Normo-glycaemia	1 (1.8)	1	1.3	5 (4.7)	5	3.4	3 (5.9)	3	4.2
Pre-diabetes	0			2 (4.5)	3	4.9	0		
T2D	0			3 (6.1)	3	4.4	2 (8.0)	2	5.6
Gastritis									
Normo-glycaemia	0			1 (0.9)	1	0.7	2 (3.9)	2	2.8
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Enterocolitis									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Chronic gastritis									
Normo-glycaemia	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			1 (4.0)	1	2.8
Enteritis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Colitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Colitis ischaemic									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Benign neoplasms gastrointestinal									
Normo-glycaemia	2 (3.6)	2	2.7	2 (1.9)	2	1.4	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	4	6.5	0		
T2D	0			1 (2.0)	1	1.5	0		
Gastric polyps									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			3 (6.8)	3	4.9	0		
T2D	0			0			0		
Large intestine polyp									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Rectal polyp									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Oral soft tissue conditions									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	0		
Stomatitis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Angular cheilitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Anal and rectal conditions NEC									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	0			0			0		
Anal fissure									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	0			0			0		
Gastrointestinal ulceration and perforation									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	2	3.3	0		
T2D	0			0			0		
Erosive duodenitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Gastritis erosive									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Gastrointestinal vascular conditions									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Haemorrhoids									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Diverticular disorders									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Diverticulum intestinal									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Gastrointestinal haemorrhages NEC									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Anal haemorrhage									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Mallory-Weiss syndrome									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Gastrointestinal stenosis and obstruction									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Intestinal obstruction									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Salivary gland conditions									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Parotid gland enlargement									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Infections and infestations									
Normo-glycaemia	21 (38.2)	33	44.5	38 (35.8)	65	44.6	20 (39.2)	35	49.1
Pre-diabetes	5 (25.0)	11	41.4	22 (50.0)	39	63.9	7 (28.0)	7	20.1
T2D	16 (64.0)	20	56.3	20 (40.8)	49	71.8	8 (32.0)	11	30.9
Infections - pathogen unspecified									
Normo-glycaemia	19 (34.5)	28	37.8	34 (32.1)	55	37.8	20 (39.2)	35	49.1
Pre-diabetes	5 (25.0)	11	41.4	20 (45.5)	36	58.9	7 (28.0)	7	20.1
T2D	15 (60.0)	19	53.5	17 (34.7)	41	60.1	7 (28.0)	9	25.3
Nasopharyngitis									
Normo-glycaemia	12 (21.8)	17	22.9	25 (23.6)	37	25.4	10 (19.6)	15	21.0
Pre-diabetes	2 (10.0)	7	26.3	15 (34.1)	25	40.9	4 (16.0)	4	11.5
T2D	10 (40.0)	12	33.8	13 (26.5)	19	27.8	4 (16.0)	5	14.0
Gastroenteritis									
Normo-glycaemia	4 (7.3)	5	6.7	5 (4.7)	5	3.4	0		
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	3	4.9	1 (4.0)	1	2.9
T2D	2 (8.0)	2	5.6	3 (6.1)	5	7.3	0		
Bronchitis									
Normo-glycaemia	2 (3.6)	2	2.7	1 (0.9)	2	1.4	0		
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	1 (4.0)	1	2.8	3 (6.1)	5	7.3	0		
Cystitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			2 (4.1)	2	2.9	0		
Pharyngitis									
Normo-glycaemia	3 (5.5)	3	4.0	1 (0.9)	1	0.7	3 (5.9)	4	5.6
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			2 (4.1)	3	4.4	0		
Conjunctivitis									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			2 (4.5)	3	4.9	0		
T2D	0			0			1 (4.0)	1	2.8
Diverticulitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Enteritis infectious									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Gingivitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Acute sinusitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			1 (2.0)	1	1.5	0		
Folliculitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	2	2.9	0		
Hordeolum									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			1 (2.0)	1	1.5	0		
Urinary tract infection									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	3	4.4	0		
Rhinitis									
Normo-glycaemia	0			2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	0			0		
Tonsillitis									
Normo-glycaemia	0			2 (1.9)	2	1.4	2 (3.9)	3	4.2
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Pelvic inflammatory disease									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Pyelonephritis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Pyelonephritis acute									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Sinusitis									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			2 (8.0)	2	5.6
Urethritis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Periodontitis									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Pyoderma									
Normo-glycaemia	0			0			1 (2.0)	2	2.8
Pre-diabetes	0			0			0		
T2D	0			0			0		
Upper respiratory tract infection									
Normo-glycaemia	0			0			2 (3.9)	3	4.2
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Vaginal infection									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Viral infectious disorders									
Normo-glycaemia	4 (7.3)	4	5.4	6 (5.7)	7	4.8	0		
Pre-diabetes	0			3 (6.8)	3	4.9	0		
T2D	1 (4.0)	1	2.8	4 (8.2)	4	5.9	1 (4.0)	1	2.8
Influenza									
Normo-glycaemia	2 (3.6)	2	2.7	4 (3.8)	4	2.7	0		
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	0			2 (4.1)	2	2.9	1 (4.0)	1	2.8
Herpes zoster									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Gastroenteritis viral									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Herpes simplex									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Infectious mononucleosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Bacterial infectious disorders									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			2 (4.1)	3	4.4	1 (4.0)	1	2.8
Alpha haemolytic streptococcal infection									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Erysipelas									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	2	2.9	0		
Cellulitis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Furuncle									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Helicobacter infection									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Fungal infectious disorders									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Tinea pedis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Vulvovaginal candidiasis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Musculoskeletal and connective tissue disorders									
Normo-glycaemia	10 (18.2)	18	24.3	26 (24.5)	30	20.6	9 (17.6)	14	19.6
Pre-diabetes	4 (20.0)	4	15.1	6 (13.6)	6	9.8	7 (28.0)	9	25.8
T2D	10 (40.0)	12	33.8	11 (22.4)	16	23.4	8 (32.0)	11	30.9
Musculoskeletal and connective tissue disorders NEC									
Normo-glycaemia	6 (10.9)	10	13.5	12 (11.3)	12	8.2	6 (11.8)	7	9.8
Pre-diabetes	2 (10.0)	2	7.5	5 (11.4)	5	8.2	3 (12.0)	3	8.6
T2D	2 (8.0)	2	5.6	5 (10.2)	6	8.8	4 (16.0)	5	14.0
Back pain									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	5 (9.1)	9	12.1	9 (8.5)	9	6.2	4 (7.8)	5	7.0
Pre-diabetes	2 (10.0)	2	7.5	5 (11.4)	5	8.2	3 (12.0)	3	8.6
T2D	1 (4.0)	1	2.8	5 (10.2)	6	8.8	2 (8.0)	3	8.4
Musculoskeletal discomfort									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Neck pain									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Pain in extremity									
Normo-glycaemia	0			1 (0.9)	1	0.7	2 (3.9)	2	2.8
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Musculoskeletal pain									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Musculoskeletal stiffness									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Joint disorders									
Normo-glycaemia	5 (9.1)	6	8.1	8 (7.5)	8	5.5	3 (5.9)	5	7.0
Pre-diabetes	2 (10.0)	2	7.5	0			4 (16.0)	6	17.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	8 (32.0)	9	25.3	5 (10.2)	5	7.3	4 (16.0)	5	14.0
Arthralgia									
Normo-glycaemia	3 (5.5)	4	5.4	3 (2.8)	3	2.1	3 (5.9)	5	7.0
Pre-diabetes	1 (5.0)	1	3.8	0			1 (4.0)	2	5.7
T2D	5 (20.0)	5	14.1	2 (4.1)	2	2.9	2 (8.0)	2	5.6
Periarthritis									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	2 (4.1)	2	2.9	0		
Rotator cuff syndrome									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			1 (2.0)	1	1.5	0		
Osteoarthritis									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			2 (8.0)	2	5.7
T2D	2 (8.0)	2	5.6	0			0		
Spinal osteoarthritis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Arthritis									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Articular calcification									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	2	5.6
Muscle disorders									
Normo-glycaemia	1 (1.8)	1	1.3	6 (5.7)	6	4.1	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			2 (4.1)	2	2.9	0		
Myalgia									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			2 (4.1)	2	2.9	0		
Muscle spasms									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Fibromyalgia									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Rhabdomyolysis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Tendon, ligament and cartilage disorders									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			0		
T2D	0			2 (4.1)	3	4.4	0		
Tendonitis									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Trigger finger									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	2	2.9	0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Intervertebral disc protrusion									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	1	2.8
Spinal stenosis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Synovial and bursal disorders									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			0		
T2D	0			0			0		
Bursitis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Synovitis									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Nervous system disorders									
Normo-glycaemia	8 (14.5)	11	14.8	21 (19.8)	32	22.0	3 (5.9)	3	4.2
Pre-diabetes	0			3 (6.8)	5	8.2	2 (8.0)	2	5.7
T2D	0			11 (22.4)	15	22.0	1 (4.0)	1	2.8
Neurological disorders NEC									
Normo-glycaemia	6 (10.9)	8	10.8	16 (15.1)	25	17.2	2 (3.9)	2	2.8
Pre-diabetes	0			2 (4.5)	3	4.9	1 (4.0)	1	2.9
T2D	0			4 (8.2)	5	7.3	0		
Dizziness									
Normo-glycaemia	3 (5.5)	5	6.7	12 (11.3)	17	11.7	0		
Pre-diabetes	0			0			0		
T2D	0			2 (4.1)	2	2.9	0		
Hypoaesthesia									
Normo-glycaemia	2 (3.6)	2	2.7	1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			1 (2.0)	2	2.9	0		
Dizziness postural									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	2	3.3	0		
T2D	0			0			0		
Somnolence									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Dysaesthesia									
Normo-glycaemia	0			1 (0.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Dysgeusia									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Neuralgia									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Neurological symptom									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Paraesthesia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Taste disorder									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Intercostal neuralgia									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Sensory loss									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Headaches									
Normo-glycaemia	2 (3.6)	2	2.7	6 (5.7)	6	4.1	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	1 (4.0)	1	2.9
T2D	0			3 (6.1)	5	7.3	1 (4.0)	1	2.8
Headache									
Normo-glycaemia	2 (3.6)	2	2.7	6 (5.7)	6	4.1	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	1 (4.0)	1	2.9
T2D	0			3 (6.1)	5	7.3	1 (4.0)	1	2.8
Spinal cord and nerve root disorders									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
T2D	0				3	(6.1)	3	4.4	0			
Sciatica												
Normo-glycaemia	1	(1.8)	1	1.3	0				0			
Pre-diabetes	0				0				0			
T2D	0				3	(6.1)	3	4.4	0			
Peripheral neuropathies												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				1	(2.3)	1	1.6	0			
T2D	0				0				0			
Carpal tunnel syndrome												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				1	(2.3)	1	1.6	0			
T2D	0				0				0			
Cranial nerve disorders (excl neoplasms)												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Parosmia												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Neuromuscular disorders												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Autonomic nervous system imbalance									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Central nervous system vascular disorders									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Lacunar infarction									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Injury, poisoning and procedural complications									
Normo-glycaemia	6 (10.9)	6	8.1	12 (11.3)	12	8.2	7 (13.7)	8	11.2
Pre-diabetes	7 (35.0)	10	37.6	6 (13.6)	7	11.5	4 (16.0)	5	14.3
T2D	2 (8.0)	3	8.4	7 (14.3)	7	10.3	1 (4.0)	1	2.8
Injuries NEC									
Normo-glycaemia	2 (3.6)	2	2.7	6 (5.7)	6	4.1	5 (9.8)	6	8.4
Pre-diabetes	3 (15.0)	6	22.6	5 (11.4)	6	9.8	4 (16.0)	4	11.5
T2D	1 (4.0)	2	5.6	6 (12.2)	6	8.8	0		
Ligament sprain									
Normo-glycaemia	1 (1.8)	1	1.3	0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	3	4.9	1 (4.0)	1	2.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	2	5.6	0			0		
Contusion									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	2 (10.0)	2	7.5	1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	0		
Tendon rupture									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			1 (2.0)	1	1.5	0		
Arthropod sting									
Normo-glycaemia	0			3 (2.8)	3	2.1	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Epicondylitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Post-traumatic neck syndrome									
Normo-glycaemia	0			0			2 (3.9)	2	2.8
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Arthropod bite									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Limb injury									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Subcutaneous haematoma									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Tooth fracture									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Limb crushing injury									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Muscle contusion									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Muscle strain									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	2	7.5	0			0		
T2D	0			0			0		
Road traffic accident									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Skin laceration									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Subdural haematoma									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Bone and joint injuries									
Normo-glycaemia	2 (3.6)	2	2.7	2 (1.9)	2	1.4	0		
Pre-diabetes	3 (15.0)	3	11.3	1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Radius fracture									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			1 (4.0)	1	2.8
Ankle fracture									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Meniscus injury									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Rib fracture									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Fracture									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Joint injury									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Injuries by physical agents									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	0			1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	0			0		
Heat stroke									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Thermal burn									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	1 (5.0)	1	3.8	0			1 (4.0)	1	2.9
T2D	0			0			0		
Heat illness									
Normo-glycaemia	1 (1.8)	1	1.3	0			2 (3.9)	2	2.8
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Medication errors and other product use errors and issues									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Accidental overdose									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Product administration error									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Metabolism and nutrition disorders									
Normo-glycaemia	3 (5.5)	3	4.0	10 (9.4)	10	6.9	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	7 (15.9)	7	11.5	3 (12.0)	4	11.5
T2D	2 (8.0)	2	5.6	6 (12.2)	7	10.3	4 (16.0)	6	16.8
Appetite and general nutritional disorders									
Normo-glycaemia	2 (3.6)	2	2.7	7 (6.6)	7	4.8	0		
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	3	4.9	0		
T2D	2 (8.0)	2	5.6	3 (6.1)	3	4.4	0		
Decreased appetite									
Normo-glycaemia	2 (3.6)	2	2.7	7 (6.6)	7	4.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	3	4.9	0		
T2D	2 (8.0)	2	5.6	3 (6.1)	3	4.4	0		
Purine and pyrimidine metabolism disorders									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			3 (6.8)	3	4.9	1 (4.0)	1	2.9
T2D	0			0			3 (12.0)	4	11.2
Hyperuricaemia									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			2 (4.5)	2	3.3	1 (4.0)	1	2.9
T2D	0			0			2 (8.0)	2	5.6
Gout									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			1 (4.0)	2	5.6
Glucose metabolism disorders (incl diabetes mellitus)									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			2 (8.0)	3	8.6
T2D	0			2 (4.1)	3	4.4	1 (4.0)	1	2.8
Diabetes mellitus									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Type 2 diabetes mellitus									
Normo-glycaemia	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Pre-diabetes	0			0			1	(4.0)	1 2.9
T2D	0			1	(2.0)	2 2.9	0		
Glucose tolerance impaired									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1	(4.0)	2 5.7
T2D	0			0			0		
Lipid metabolism disorders									
Normo-glycaemia	0			1	(0.9)	1 0.7	1	(2.0)	1 1.4
Pre-diabetes	0			1	(2.3)	1 1.6	0		
T2D	0			0			1	(4.0)	1 2.8
Dyslipidaemia									
Normo-glycaemia	0			1	(0.9)	1 0.7	1	(2.0)	1 1.4
Pre-diabetes	0			1	(2.3)	1 1.6	0		
T2D	0			0			1	(4.0)	1 2.8
Electrolyte and fluid balance conditions									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Dehydration									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Metabolism disorders NEC									
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Hypercreatininaemia									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Normo-glycaemia	6 (10.9)	7	9.4	14 (13.2)	16	11.0	10 (19.6)	15	21.0
Pre-diabetes	2 (10.0)	3	11.3	5 (11.4)	5	8.2	3 (12.0)	4	11.5
T2D	2 (8.0)	3	8.4	5 (10.2)	6	8.8	0		
Respiratory tract signs and symptoms									
Normo-glycaemia	2 (3.6)	3	4.0	10 (9.4)	12	8.2	8 (15.7)	11	15.4
Pre-diabetes	2 (10.0)	2	7.5	3 (6.8)	3	4.9	3 (12.0)	4	11.5
T2D	2 (8.0)	2	5.6	2 (4.1)	2	2.9	0		
Upper respiratory tract inflammation									
Normo-glycaemia	1 (1.8)	2	2.7	7 (6.6)	9	6.2	7 (13.7)	10	14.0
Pre-diabetes	2 (10.0)	2	7.5	3 (6.8)	3	4.9	2 (8.0)	3	8.6
T2D	2 (8.0)	2	5.6	1 (2.0)	1	1.5	0		
Hiccups									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Oropharyngeal pain									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			1 (4.0)	1	2.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Rhinorrhoea									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Upper respiratory tract disorders (excl infections)									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	1 (2.0)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	2 (4.5)	2	3.3	0		
T2D	0			2 (4.1)	2	2.9	0		
Rhinitis allergic									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	2	2.8
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	0			2 (4.1)	2	2.9	0		
Epistaxis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Vasomotor rhinitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Respiratory disorders NEC									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dyspnoea									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Cough									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Bronchial disorders (excl neoplasms)									
Normo-glycaemia	2 (3.6)	2	2.7	0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Asthma									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Cough variant asthma									
Normo-glycaemia	1 (1.8)	1	1.3	0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Skin and subcutaneous tissue disorders									
Normo-glycaemia	5 (9.1)	8	10.8	15 (14.2)	19	13.0	9 (17.6)	12	16.8
Pre-diabetes	3 (15.0)	7	26.3	3 (6.8)	4	6.5	1 (4.0)	1	2.9
T2D	5 (20.0)	7	19.7	6 (12.2)	7	10.3	1 (4.0)	1	2.8
Epidermal and dermal conditions									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	3 (5.5)	3	4.0	9 (8.5)	10	6.9	7 (13.7)	9	12.6
Pre-diabetes	3 (15.0)	5	18.8	3 (6.8)	3	4.9	0		
T2D	4 (16.0)	5	14.1	5 (10.2)	6	8.8	1 (4.0)	1	2.8
Pruritus									
Normo-glycaemia	0			1 (0.9)	1	0.7	2 (3.9)	3	4.2
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	0		
Eczema									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	3 (12.0)	3	8.4	1 (2.0)	1	1.5	1 (4.0)	1	2.8
Dermatitis									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	2	2.9	0		
Dyshidrotic eczema									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Stasis dermatitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Dermatitis contact									
Normo-glycaemia	1 (1.8)	1	1.3	0			3 (5.9)	3	4.2
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			1 (2.0)	1	1.5	0		
Erythema									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Eczema asteatotic									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Dermatitis atopic									
Normo-glycaemia	0			1 (0.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Rash									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Drug eruption									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Dry skin									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Pain of skin									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Rash pruritic									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Seborrhoeic dermatitis									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Xanthelasma									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Skin appendage conditions									
Normo-glycaemia	2 (3.6)	2	2.7	6 (5.7)	6	4.1	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Miliaria									
Normo-glycaemia	1 (1.8)	1	1.3	0			2 (3.9)	2	2.8
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Alopecia									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	1	2.8	0			0		
Alopecia areata									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Acne									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Ingrowing nail									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Angioedema and urticaria									
Normo-glycaemia	1 (1.8)	2	2.7	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	0			0		
Urticaria									
Normo-glycaemia	1 (1.8)	2	2.7	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	0			0		
Cornification and dystrophic skin disorders									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperkeratosis									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Xeroderma									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Eye disorders									
Normo-glycaemia	2 (3.6)	2	2.7	3 (2.8)	4	2.7	3 (5.9)	3	4.2
Pre-diabetes	1 (5.0)	1	3.8	3 (6.8)	3	4.9	1 (4.0)	1	2.9
T2D	3 (12.0)	4	11.3	11 (22.4)	12	17.6	3 (12.0)	4	11.2
Retina, choroid and vitreous haemorrhages and vascular disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	1 (4.0)	2	5.6	5 (10.2)	5	7.3	2 (8.0)	2	5.6
Diabetic retinopathy									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	2	5.6	3 (6.1)	3	4.4	2 (8.0)	2	5.6
Retinal exudates									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Retinal haemorrhage												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Retinopathy												
Normo-glycaemia	0				0				0			
Pre-diabetes	1	(5.0)	1	3.8	0				0			
T2D	0				0				0			
Vision disorders												
Normo-glycaemia	0				1	(0.9)	1	0.7	0			
Pre-diabetes	0				1	(2.3)	1	1.6	0			
T2D	0				2	(4.1)	2	2.9	0			
Presbyopia												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				1	(2.3)	1	1.6	0			
T2D	0				0				0			
Amblyopia												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Visual acuity reduced												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Optic nerve disorder												
Normo-glycaemia	0				1	(0.9)	1	0.7	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Pre-diabetes	0			0			0		
T2D	0			0			0		
Anterior eye structural change, deposit and degeneration									
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			2	(4.5)	2 3.3	0		
T2D	0			0			1	(4.0)	1 2.8
Cataract									
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			2	(4.5)	2 3.3	0		
T2D	0			0			1	(4.0)	1 2.8
Ocular infections, irritations and inflammations									
Normo-glycaemia	0			0			1	(2.0)	1 1.4
Pre-diabetes	0			0			0		
T2D	1	(4.0)	1 2.8	2	(4.1)	2 2.9	0		
Conjunctivitis allergic									
Normo-glycaemia	0			0			1	(2.0)	1 1.4
Pre-diabetes	0			0			0		
T2D	1	(4.0)	1 2.8	1	(2.0)	1 1.5	0		
Ocular hyperaemia									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Glaucoma and ocular hypertension									
Normo-glycaemia	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Glaucoma									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Open angle glaucoma									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Ocular haemorrhages and vascular disorders NEC									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Optic disc haemorrhage									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Conjunctival haemorrhage									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Retinal tear									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Macular fibrosis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Rhegmatogenous retinal detachment									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Eye disorders NEC									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Lacrimal disorder									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Lacrimation increased									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dry eye									
Normo-glycaemia	1 (1.8)	1	1.3	0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Investigations									
Normo-glycaemia	6 (10.9)	7	9.4	7 (6.6)	8	5.5	5 (9.8)	5	7.0
Pre-diabetes	5 (25.0)	7	26.3	4 (9.1)	5	8.2	2 (8.0)	4	11.5
T2D	2 (8.0)	2	5.6	5 (10.2)	7	10.3	2 (8.0)	2	5.6
Enzyme investigations NEC									
Normo-glycaemia	3 (5.5)	3	4.0	3 (2.8)	3	2.1	2 (3.9)	2	2.8
Pre-diabetes	0			2 (4.5)	3	4.9	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Blood creatine phosphokinase increased									
Normo-glycaemia	3 (5.5)	3	4.0	3 (2.8)	3	2.1	2 (3.9)	2	2.8
Pre-diabetes	0			2 (4.5)	3	4.9	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Gastrointestinal investigations									
Normo-glycaemia	4 (7.3)	4	5.4	2 (1.9)	2	1.4	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	2	2.9	0		
Lipase increased									
Normo-glycaemia	2 (3.6)	2	2.7	2 (1.9)	2	1.4	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Amylase increased									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Occult blood positive									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Cardiac and vascular investigations (excl enzyme tests)									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	0			1 (2.0)	1	1.5	0		
Blood pressure decreased									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Electrocardiogram QRS complex prolonged									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Electrocardiogram QT prolonged									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hepatobiliary investigations									
Normo-glycaemia	0			1 (0.9)	1	0.7	2 (3.9)	2	2.8
Pre-diabetes	0			1 (2.3)	1	1.6	2 (8.0)	2	5.7
T2D	0			0			1 (4.0)	1	2.8
Liver function test increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	2 (8.0)	2	5.7
T2D	0			0			0		
Aspartate aminotransferase increased									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Alanine aminotransferase increased									
Normo-glycaemia	0			0			2 (3.9)	2	2.8
Pre-diabetes	0			0			0		
T2D	0			0			0		
Blood bilirubin increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Endocrine investigations (incl sex hormones)									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Blood thyroid stimulating hormone decreased												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Haematology investigations (incl blood groups)												
Normo-glycaemia	0				0				0			
Pre-diabetes	1	(5.0)	2	7.5	0				0			
T2D	0				1	(2.0)	1	1.5	0			
Haemoglobin decreased												
Normo-glycaemia	0				0				0			
Pre-diabetes	0				0				0			
T2D	0				1	(2.0)	1	1.5	0			
Lymphocyte count decreased												
Normo-glycaemia	0				0				0			
Pre-diabetes	1	(5.0)	1	3.8	0				0			
T2D	0				0				0			
White blood cell count increased												
Normo-glycaemia	0				0				0			
Pre-diabetes	1	(5.0)	1	3.8	0				0			
T2D	0				0				0			
Physical examination and organ system status topics												
Normo-glycaemia	0				0				0			
Pre-diabetes	1	(5.0)	1	3.8	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			1 (2.0)	1	1.5	0		
Weight decreased									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			1 (2.0)	1	1.5	0		
Lipid analyses									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Blood triglycerides increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Metabolic, nutritional and blood gas investigations									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			1 (4.0)	1	2.8
Blood uric acid increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			1 (4.0)	1	2.9
T2D	0			0			0		
Glycosylated haemoglobin increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Protein and chemistry analyses NEC									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
C-reactive protein increased									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Water, electrolyte and mineral investigations									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Blood potassium increased									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
General disorders and administration site conditions									
Normo-glycaemia	2 (3.6)	4	5.4	8 (7.5)	12	8.2	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	2	3.3	0		
T2D	1 (4.0)	1	2.8	7 (14.3)	21	30.8	1 (4.0)	1	2.8
General system disorders NEC									
Normo-glycaemia	1 (1.8)	3	4.0	5 (4.7)	8	5.5	0		
Pre-diabetes	0			1 (2.3)	2	3.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	1 (4.0)	1	2.8	5 (10.2)	8	11.7	1 (4.0)	1	2.8
Malaise									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			1 (2.3)	2	3.3	0		
T2D	1 (4.0)	1	2.8	3 (6.1)	5	7.3	0		
Feeling abnormal									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Fatigue									
Normo-glycaemia	0			3 (2.8)	3	2.1	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Non-cardiac chest pain									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Oedema peripheral									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Influenza like illness									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Pain									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Thirst									
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hangover									
Normo-glycaemia	1	(1.8)	3 4.0	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hunger									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1	(4.0)	1 2.8
Administration site reactions									
Normo-glycaemia	0			2	(1.9)	2 1.4	0		
Pre-diabetes	0			0			0		
T2D	0			2	(4.1)	13 19.0	0		
Injection site erythema									
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	12 17.6	0		
Injection site dermatitis									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			1 (2.0)	1	1.5	0		
Injection site discomfort									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Body temperature conditions									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Pyrexia									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Vascular disorders									
Normo-glycaemia	1 (1.8)	1	1.3	7 (6.6)	7	4.8	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	2 (4.5)	2	3.3	2 (8.0)	2	5.7
T2D	0			2 (4.1)	2	2.9	0		
Decreased and nonspecific blood pressure disorders and shock									
Normo-glycaemia	0			3 (2.8)	3	2.1	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			1 (2.0)	1	1.5	0		
Orthostatic hypotension									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Hypotension									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Vascular hypertensive disorders									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	2 (8.0)	2	5.7
T2D	0			0			0		
Hypertension									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	2 (8.0)	2	5.7
T2D	0			0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Arteriosclerosis									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Embolism and thrombosis									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Venous thrombosis limb									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Reproductive system and breast disorders									
Normo-glycaemia	2 (3.6)	3	4.0	6 (5.7)	7	4.8	0		
Pre-diabetes	0			2 (4.5)	2	3.3	0		
T2D	1 (4.0)	1	2.8	1 (2.0)	1	1.5	0		
Menstrual cycle and uterine bleeding disorders									
Normo-glycaemia	0			3 (2.8)	3	2.1	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Dysmenorrhoea									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Menstrual disorder									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Menstruation irregular									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Breast disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Breast calcifications									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Menopause related conditions									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Menopausal symptoms									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Prostatic disorders (excl infections and inflammations)									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Benign prostatic hyperplasia									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Male reproductive tract infections and inflammations									
Normo-glycaemia	0			1 (0.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Prostatitis									
Normo-glycaemia	0			1 (0.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Uterine, pelvic and broad ligament disorders									
Normo-glycaemia	1 (1.8)	2	2.7	0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Endometrial hyperplasia									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Endometriosis									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Uterine haemorrhage									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Psychiatric disorders									
Normo-glycaemia	1 (1.8)	1	1.3	4 (3.8)	4	2.7	0		
Pre-diabetes	3 (15.0)	3	11.3	0			0		
T2D	0			2 (4.1)	2	2.9	1 (4.0)	1	2.8
Sleep disorders and disturbances									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	0		
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	0			1 (2.0)	1	1.5	0		
Insomnia									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	0		
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	0			1 (2.0)	1	1.5	0		
Depressed mood disorders and disturbances									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Depression									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Mood disorders and disturbances NEC									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Emotional disorder									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Normo-glycaemia	0			1	(0.9)	1 0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Listless									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1	(4.0)	1 2.8
Adjustment disorders (incl subtypes)									
Normo-glycaemia	0			0			0		
Pre-diabetes	1	(5.0)	1 3.8	0			0		
T2D	0			0			0		
Adjustment disorder									
Normo-glycaemia	0			0			0		
Pre-diabetes	1	(5.0)	1 3.8	0			0		
T2D	0			0			0		
Ear and labyrinth disorders									
Normo-glycaemia	3	(5.5)	3 4.0	1	(0.9)	1 0.7	1	(2.0)	1 1.4
Pre-diabetes	0			2	(4.5)	2 3.3	0		
T2D	1	(4.0)	1 2.8	0			0		
Hearing disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			2	(4.5)	2 3.3	0		
T2D	0			0			0		
Deafness									
Normo-glycaemia	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Deafness neurosensory									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	0			0			0		
Inner ear and VIIIth cranial nerve disorders									
Normo-glycaemia	3 (5.5)	3	4.0	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Vertigo									
Normo-glycaemia	2 (3.6)	2	2.7	1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Tinnitus									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Cardiac disorders									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	2 (3.9)	2	2.8
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Cardiac arrhythmias									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	1 (2.0)	1	1.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	1 (4.0)	1	2.8
Tachycardia									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Ventricular extrasystoles									
Normo-glycaemia	1 (1.8)	1	1.3	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Arrhythmia									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Atrial fibrillation									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Cardiac disorders, signs and symptoms NEC									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Palpitations									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
T2D	0			0			0		
Coronary artery disorders									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Acute myocardial infarction									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hepatobiliary disorders									
Normo-glycaemia	1 (1.8)	1	1.3	5 (4.7)	5	3.4	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			1 (4.0)	1	2.8
Gallbladder disorders									
Normo-glycaemia	1 (1.8)	1	1.3	3 (2.8)	3	2.1	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Cholelithiasis									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Gallbladder polyp									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperplastic cholecystopathy									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hepatic and hepatobiliary disorders									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			1 (4.0)	1	2.8
Hepatic cyst									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hepatic function abnormal									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Alcoholic liver disease									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Hepatic steatosis									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Renal and urinary disorders									
Normo-glycaemia	2 (3.6)	3	4.0	5 (4.7)	5	3.4	3 (5.9)	4	5.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	1 (4.0)	1	2.8	0			2 (8.0)	3	8.4
Renal disorders (excl nephropathies)									
Normo-glycaemia	0			2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Azotaemia									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Renal cyst									
Normo-glycaemia	0			1 (0.9)	1	0.7	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Urolithiases									
Normo-glycaemia	0			2 (1.9)	2	1.4	2 (3.9)	3	4.2
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	2	5.6
Ureterolithiasis									
Normo-glycaemia	0			2 (1.9)	2	1.4	1 (2.0)	2	2.8
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			1 (4.0)	2	5.6
Calculus urinary									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	2 (10.0)	2	7.5	0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urinary tract signs and symptoms									
Normo-glycaemia	1 (1.8)	2	2.7	1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Hyperuricosuria									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Nocturia									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Proteinuria									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Nephropathies									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Diabetic nephropathy									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			0			1 (4.0)	1	2.8
Nephropathy toxic									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Pre-diabetes	0			0			0		
T2D	0			0			0		
Congenital, familial and genetic disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			2	(4.1)	2 2.9	0		
Gastrointestinal tract disorders congenital									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Diverticulitis Meckel's									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Skin and subcutaneous tissue disorders congenital									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		
Birth mark									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1	(2.0)	1 1.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Immune system disorders									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	0			0		
Allergic conditions									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	0			0		
Seasonal allergy									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			1 (2.3)	1	1.6	0		
T2D	1 (4.0)	1	2.8	0			0		
Food allergy									
Normo-glycaemia	0			0			0		
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Endocrine disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Thyroid gland disorders									
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Hyperthyroidism									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Normo-glycaemia	0			0			0		
Pre-diabetes	0			0			0		
T2D	0			1 (2.0)	1	1.5	0		
Blood and lymphatic system disorders									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Anaemias nonhaemolytic and marrow depression									
Normo-glycaemia	0			2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Iron deficiency anaemia									
Normo-glycaemia	0			2 (1.9)	2	1.4	0		
Pre-diabetes	0			0			0		
T2D	1 (4.0)	1	2.8	0			0		
Anaemia									
Normo-glycaemia	0			0			1 (2.0)	1	1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Spleen, lymphatic and reticuloendothelial system disorders									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lymphadenitis									
Normo-glycaemia	1 (1.8)	1	1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Normo-glycaemia	1 (1.8)	1	1.3	2 (1.9)	2	1.4	1 (2.0)	1	1.4
Pre-diabetes	1 (5.0)	1	3.8	0			0		
T2D	0			0			0		
Gastrointestinal neoplasms benign									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Intraductal papillary mucinous neoplasm									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Reproductive neoplasms female benign									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Uterine leiomyoma									
Normo-glycaemia	0			1 (0.9)	1	0.7	0		
Pre-diabetes	0			0			0		
T2D	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hepatobiliary neoplasms malignant and unspecified									
Normo-glycaemia	0			0			0		
Pre-diabetes	1	(5.0)	1 3.8	0			0		
T2D	0			0			0		
Bile duct adenocarcinoma									
Normo-glycaemia	0			0			0		
Pre-diabetes	1	(5.0)	1 3.8	0			0		
T2D	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
Normo-glycaemia	1	(1.8)	1 1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Clear cell renal cell carcinoma									
Normo-glycaemia	1	(1.8)	1 1.3	0			0		
Pre-diabetes	0			0			0		
T2D	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Normo-glycaemia	0			0			1	(2.0)	1 1.4
Pre-diabetes	0			0			0		
T2D	0			0			0		
Lung neoplasm malignant									
Normo-glycaemia	0			0			1	(2.0)	1 1.4
Pre-diabetes	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by glycaemic status at baseline, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
T2D	0				0				0			
Surgical and medical procedures												
Normo-glycaemia	0				1	(0.9)	1	0.7	0			
Pre-diabetes	0				0				0			
T2D	0				0				0			
Gastrointestinal therapeutic procedures												
Normo-glycaemia	0				1	(0.9)	1	0.7	0			
Pre-diabetes	0				0				0			
T2D	0				0				0			
Large intestinal polypectomy												
Normo-glycaemia	0				1	(0.9)	1	0.7	0			
Pre-diabetes	0				0				0			
T2D	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
T2D: Type 2 diabetes
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

47 Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Diabetes treatment group 1	243	317.3			231	306.7			230	303.0		
Diabetes treatment group 2	159	212.5			172	226.3			172	225.3		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Diabetes treatment group 1	194	(79.8)	1033	325.6	194	(84.0)	1165	379.8	184	(80.0)	856	282.5
Diabetes treatment group 2	135	(84.9)	826	388.7	159	(92.4)	1032	456.0	125	(72.7)	532	236.1
Serious												
Yes												
Diabetes treatment group 1	17	(7.0)	21	6.6	21	(9.1)	28	9.1	20	(8.7)	33	10.9
Diabetes treatment group 2	14	(8.8)	32	15.1	19	(11.0)	43	19.0	17	(9.9)	20	8.9
No												
Diabetes treatment group 1	193	(79.4)	1012	319.0	193	(83.5)	1137	370.7	184	(80.0)	823	271.6
Diabetes treatment group 2	133	(83.6)	794	373.6	159	(92.4)	989	437.0	123	(71.5)	512	227.3
Severity												
Severe												
Diabetes treatment group 1	10	(4.1)	13	4.1	14	(6.1)	19	6.2	19	(8.3)	27	8.9
Diabetes treatment group 2	12	(7.5)	30	14.1	13	(7.6)	32	14.1	9	(5.2)	12	5.3
Moderate												
Diabetes treatment group 1	82	(33.7)	186	58.6	98	(42.4)	310	101.1	70	(30.4)	163	53.8
Diabetes treatment group 2	53	(33.3)	129	60.7	75	(43.6)	198	87.5	48	(27.9)	101	44.8

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severity												
Mild												
Diabetes treatment group 1	178	(73.3)	834	262.9	180	(77.9)	836	272.5	168	(73.0)	666	219.8
Diabetes treatment group 2	128	(80.5)	667	313.9	148	(86.0)	802	354.4	111	(64.5)	419	186.0
Relationship to trial product												
Missing												
Diabetes treatment group 1	7	(2.9)	7	2.2	5	(2.2)	5	1.6	3	(1.3)	3	1.0
Diabetes treatment group 2	3	(1.9)	4	1.9	5	(2.9)	5	2.2	3	(1.7)	4	1.8
Probable												
Diabetes treatment group 1	76	(31.3)	187	58.9	91	(39.4)	223	72.7	34	(14.8)	56	18.5
Diabetes treatment group 2	57	(35.8)	157	73.9	78	(45.3)	233	103.0	28	(16.3)	44	19.5
Possible												
Diabetes treatment group 1	92	(37.9)	210	66.2	95	(41.1)	296	96.5	57	(24.8)	104	34.3
Diabetes treatment group 2	61	(38.4)	197	92.7	87	(50.6)	238	105.2	36	(20.9)	66	29.3
Unlikely												
Diabetes treatment group 1	175	(72.0)	629	198.3	162	(70.1)	641	209.0	171	(74.3)	693	228.7
Diabetes treatment group 2	121	(76.1)	468	220.2	139	(80.8)	556	245.7	118	(68.6)	418	185.5
Outcome												
Fatal												
Diabetes treatment group 1	0				1	(0.4)	1	0.3	0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4
Recovered												
Diabetes treatment group 1	184	(75.7)	839	264.4	182	(78.8)	949	309.4	170	(73.9)	666	219.8

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Outcome												
Recovered												
Diabetes treatment group 2	131	(82.4)	664	312.5	151	(87.8)	863	381.3	115	(66.9)	388	172.2
Recovering												
Diabetes treatment group 1	6	(2.5)	13	4.1	7	(3.0)	9	2.9	12	(5.2)	14	4.6
Diabetes treatment group 2	13	(8.2)	19	8.9	10	(5.8)	17	7.5	5	(2.9)	5	2.2
Recovered With Sequelae												
Diabetes treatment group 1	3	(1.2)	3	0.9	2	(0.9)	2	0.7	1	(0.4)	1	0.3
Diabetes treatment group 2	2	(1.3)	2	0.9	3	(1.7)	3	1.3	0			
Not Recovered												
Diabetes treatment group 1	81	(33.3)	178	56.1	91	(39.4)	202	65.9	88	(38.3)	175	57.7
Diabetes treatment group 2	66	(41.5)	141	66.4	72	(41.9)	143	63.2	68	(39.5)	135	59.9
Unknown												
Diabetes treatment group 1	0				2	(0.9)	2	0.7	0			
Diabetes treatment group 2	0				2	(1.2)	6	2.7	3	(1.7)	3	1.3
Leading to												
Permanent treatment discontinuation												
Diabetes treatment group 1	12	(4.9)	15	4.7	9	(3.9)	13	4.2	10	(4.3)	14	4.6
Diabetes treatment group 2	8	(5.0)	8	3.8	16	(9.3)	21	9.3	4	(2.3)	4	1.8
Temporary interruption of trial product												
Diabetes treatment group 1	14	(5.8)	24	7.6	22	(9.5)	50	16.3	8	(3.5)	13	4.3
Diabetes treatment group 2	12	(7.5)	23	10.8	15	(8.7)	40	17.7	7	(4.1)	7	3.1
Dose reduction of trial product												
Diabetes treatment group 1	12	(4.9)	19	6.0	18	(7.8)	35	11.4	3	(1.3)	3	1.0
Diabetes treatment group 2	6	(3.8)	9	4.2	17	(9.9)	31	13.7	0			

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

48 Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Diabetes treatment group 1	243		317.3		231		306.7		230		303.0	
Diabetes treatment group 2	159		212.5		172		226.3		172		225.3	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Diabetes treatment group 1	194	(79.8)	1033	325.6	194	(84.0)	1165	379.8	184	(80.0)	856	282.5
Diabetes treatment group 2	135	(84.9)	826	388.7	159	(92.4)	1032	456.0	125	(72.7)	532	236.1
Gastrointestinal disorders												
Diabetes treatment group 1	142	(58.4)	392	123.6	137	(59.3)	457	149.0	78	(33.9)	143	47.2
Diabetes treatment group 2	89	(56.0)	332	156.2	119	(69.2)	467	206.4	60	(34.9)	119	52.8
Gastrointestinal signs and symptoms												
Diabetes treatment group 1	113	(46.5)	235	74.1	104	(45.0)	280	91.3	46	(20.0)	67	22.1
Diabetes treatment group 2	74	(46.5)	197	92.7	96	(55.8)	321	141.8	30	(17.4)	48	21.3
Nausea												
Diabetes treatment group 1	76	(31.3)	114	35.9	70	(30.3)	123	40.1	22	(9.6)	27	8.9
Diabetes treatment group 2	53	(33.3)	84	39.5	66	(38.4)	126	55.7	15	(8.7)	18	8.0
Vomiting												
Diabetes treatment group 1	31	(12.8)	49	15.4	43	(18.6)	83	27.1	7	(3.0)	7	2.3
Diabetes treatment group 2	23	(14.5)	44	20.7	45	(26.2)	105	46.4	4	(2.3)	5	2.2
Dyspepsia												

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	14 (5.8)	14	4.4	11 (4.8)	11	3.6	2 (0.9)	2	0.7
Diabetes treatment group 2	13 (8.2)	13	6.1	14 (8.1)	19	8.4	3 (1.7)	3	1.3
Abdominal distension									
Diabetes treatment group 1	3 (1.2)	4	1.3	9 (3.9)	12	3.9	7 (3.0)	9	3.0
Diabetes treatment group 2	6 (3.8)	8	3.8	15 (8.7)	18	8.0	4 (2.3)	4	1.8
Abdominal pain upper									
Diabetes treatment group 1	6 (2.5)	6	1.9	6 (2.6)	8	2.6	6 (2.6)	6	2.0
Diabetes treatment group 2	5 (3.1)	5	2.4	10 (5.8)	13	5.7	5 (2.9)	7	3.1
Flatulence									
Diabetes treatment group 1	16 (6.6)	17	5.4	7 (3.0)	9	2.9	4 (1.7)	5	1.6
Diabetes treatment group 2	5 (3.1)	8	3.8	9 (5.2)	12	5.3	3 (1.7)	4	1.8
Eructation									
Diabetes treatment group 1	6 (2.5)	8	2.5	11 (4.8)	15	4.9	1 (0.4)	1	0.3
Diabetes treatment group 2	5 (3.1)	8	3.8	5 (2.9)	6	2.7	0		
Abdominal pain									
Diabetes treatment group 1	7 (2.9)	8	2.5	6 (2.6)	6	2.0	3 (1.3)	3	1.0
Diabetes treatment group 2	10 (6.3)	12	5.6	7 (4.1)	9	4.0	2 (1.2)	2	0.9
Abdominal discomfort									
Diabetes treatment group 1	8 (3.3)	8	2.5	8 (3.5)	8	2.6	5 (2.2)	5	1.6
Diabetes treatment group 2	7 (4.4)	9	4.2	5 (2.9)	7	3.1	2 (1.2)	2	0.9
Abdominal pain lower									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	2 (1.2)	2	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Regurgitation									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Abnormal faeces									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Aerophagia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Epigastric discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Gastrointestinal pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal sounds abnormal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Abdominal rigidity									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Anal incontinence									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Breath odour									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Dysphagia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Faeces discoloured									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Faeces soft									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Retching									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal motility and defaecation conditions									
Diabetes treatment group 1	69 (28.4)	127	40.0	79 (34.2)	138	45.0	38 (16.5)	50	16.5
Diabetes treatment group 2	56 (35.2)	116	54.6	64 (37.2)	101	44.6	32 (18.6)	51	22.6
Diarrhoea									
Diabetes treatment group 1	49 (20.2)	82	25.8	47 (20.3)	82	26.7	24 (10.4)	29	9.6
Diabetes treatment group 2	40 (25.2)	76	35.8	39 (22.7)	59	26.1	24 (14.0)	37	16.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Constipation									
Diabetes treatment group 1	26 (10.7)	36	11.3	41 (17.7)	49	16.0	14 (6.1)	16	5.3
Diabetes treatment group 2	25 (15.7)	34	16.0	29 (16.9)	33	14.6	8 (4.7)	10	4.4
Gastrooesophageal reflux disease									
Diabetes treatment group 1	8 (3.3)	9	2.8	4 (1.7)	5	1.6	3 (1.3)	3	1.0
Diabetes treatment group 2	5 (3.1)	5	2.4	8 (4.7)	8	3.5	4 (2.3)	4	1.8
Gastrointestinal motility disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Change of bowel habit									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Irritable bowel syndrome									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal hypermotility									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gastrooesophageal sphincter insufficiency									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions									
Diabetes treatment group 1	6 (2.5)	6	1.9	7 (3.0)	7	2.3	2 (0.9)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	10 (5.8)	13	5.7	4 (2.3)	5	2.2
Gastritis									
Diabetes treatment group 1	4 (1.6)	4	1.3	3 (1.3)	3	1.0	1 (0.4)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	8 (4.7)	10	4.4	3 (1.7)	4	1.8
Enteritis									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Enterocolitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Duodenitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Chronic gastritis									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Colitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Gastrointestinal conditions NEC									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	5 (2.1)	5	1.6	11 (4.8)	11	3.6	3 (1.3)	3	1.0
Diabetes treatment group 2	2 (1.3)	3	1.4	7 (4.1)	10	4.4	3 (1.7)	3	1.3
Hyperchlorhydria									
Diabetes treatment group 1	4 (1.6)	4	1.3	6 (2.6)	6	2.0	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	2	0.9	5 (2.9)	8	3.5	1 (0.6)	1	0.4
Food poisoning									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	0		
Gastrointestinal disorder									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	0		
Diabetes treatment group 2	0			0			0		
Barrett's oesophagus									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Gastric disorder									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gastrointestinal melanosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Dental and gingival conditions									
Diabetes treatment group 1	4 (1.6)	4	1.3	4 (1.7)	4	1.3	5 (2.2)	5	1.6
Diabetes treatment group 2	4 (2.5)	5	2.4	6 (3.5)	7	3.1	2 (1.2)	2	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Toothache									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	3	1.4	2 (1.2)	2	0.9	0		
Dental caries									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	2 (1.2)	2	0.9
Gingival swelling									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Tooth deposit									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Periodontal disease									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Gastrointestinal vascular conditions									
Diabetes treatment group 1	2 (0.8)	4	1.3	4 (1.7)	4	1.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	5 (2.9)	5	2.2	1 (0.6)	1	0.4
Haemorrhoids									
Diabetes treatment group 1	1 (0.4)	2	0.6	4 (1.7)	4	1.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	5 (2.9)	5	2.2	0		
Haemorrhoids thrombosed									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Varices oesophageal									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Gastrointestinal haemorrhages NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	1 (0.6)	1	0.4
Haematochezia									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Mallory-Weiss syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Upper gastrointestinal haemorrhage									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Intra-abdominal haemorrhage									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Intra-abdominal haematoma									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Rectal haemorrhage									

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Salivary gland conditions									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	4	1.8	1 (0.6)	1	0.4
Dry mouth									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	0		
Salivary hypersecretion									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Parotid gland enlargement									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Noninfective sialoadenitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Abdominal hernias and other abdominal wall conditions									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	0			1 (0.6)	1	0.4	3 (1.7)	3	1.3
Abdominal wall haematoma									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Abdominal hernia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Hiatus hernia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Umbilical hernia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Inguinal hernia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Benign neoplasms gastrointestinal									
Diabetes treatment group 1	4 (1.6)	5	1.6	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Gastric polyps									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Large intestine polyp									
Diabetes treatment group 1	3 (1.2)	3	0.9	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Oral soft tissue conditions									

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			2 (0.9)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	0			0			0		
Mouth ulceration									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Stomatitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Aphthous ulcer									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Lip swelling									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Odynophagia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Diverticular disorders									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	1 (0.6)	1	0.4	2 (1.2)	2	0.9
Diverticulum intestinal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diverticulum									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	2	0.9
Gastrointestinal ulceration and perforation									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Gastritis erosive									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Diverticular perforation									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gastric ulcer									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Anal and rectal conditions NEC									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Anal fissure									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Exocrine pancreas conditions									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Pancreatitis acute									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Obstructive pancreatitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Pancreatic cyst									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal stenosis and obstruction									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Small intestinal obstruction									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Malabsorption conditions									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Malabsorption									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Peritoneal and retroperitoneal conditions												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Retroperitoneal mass												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Tongue conditions												
Diabetes treatment group 1	1	(0.4)	1	0.3	0				0			
Diabetes treatment group 2	0				0				0			
Glossodynia												
Diabetes treatment group 1	1	(0.4)	1	0.3	0				0			
Diabetes treatment group 2	0				0				0			
Infections and infestations												
Diabetes treatment group 1	92	(37.9)	178	56.1	93	(40.3)	193	62.9	111	(48.3)	236	77.9
Diabetes treatment group 2	74	(46.5)	140	65.9	86	(50.0)	152	67.2	64	(37.2)	123	54.6
Infections - pathogen unspecified												
Diabetes treatment group 1	80	(32.9)	147	46.3	84	(36.4)	161	52.5	95	(41.3)	191	63.0
Diabetes treatment group 2	66	(41.5)	103	48.5	78	(45.3)	128	56.6	52	(30.2)	90	40.0
Nasopharyngitis												
Diabetes treatment group 1	22	(9.1)	32	10.1	35	(15.2)	64	20.9	36	(15.7)	63	20.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	25 (15.7)	37	17.4	33 (19.2)	51	22.5	23 (13.4)	29	12.9
Upper respiratory tract infection									
Diabetes treatment group 1	25 (10.3)	40	12.6	22 (9.5)	26	8.5	22 (9.6)	28	9.2
Diabetes treatment group 2	12 (7.5)	14	6.6	20 (11.6)	22	9.7	16 (9.3)	22	9.8
Bronchitis									
Diabetes treatment group 1	7 (2.9)	8	2.5	6 (2.6)	8	2.6	11 (4.8)	12	4.0
Diabetes treatment group 2	3 (1.9)	3	1.4	8 (4.7)	8	3.5	2 (1.2)	3	1.3
Sinusitis									
Diabetes treatment group 1	6 (2.5)	6	1.9	7 (3.0)	10	3.3	8 (3.5)	10	3.3
Diabetes treatment group 2	0			7 (4.1)	9	4.0	3 (1.7)	3	1.3
Gastroenteritis									
Diabetes treatment group 1	10 (4.1)	11	3.5	8 (3.5)	9	2.9	11 (4.8)	12	4.0
Diabetes treatment group 2	14 (8.8)	17	8.0	6 (3.5)	6	2.7	2 (1.2)	3	1.3
Urinary tract infection									
Diabetes treatment group 1	11 (4.5)	14	4.4	10 (4.3)	13	4.2	8 (3.5)	11	3.6
Diabetes treatment group 2	6 (3.8)	7	3.3	3 (1.7)	3	1.3	4 (2.3)	5	2.2
Conjunctivitis									
Diabetes treatment group 1	2 (0.8)	4	1.3	1 (0.4)	1	0.3	2 (0.9)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	4 (2.3)	4	1.8	2 (1.2)	2	0.9
Paronychia									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Pneumonia									

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	3	1.3	1 (0.6)	1	0.4
Tonsillitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	0		
Cystitis									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	2 (1.2)	3	1.3
Pharyngitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	6 (2.6)	6	2.0
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Gastrointestinal infection									
Diabetes treatment group 1	0			2 (0.9)	3	1.0	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Lower respiratory tract infection									
Diabetes treatment group 1	3 (1.2)	3	0.9	2 (0.9)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	2	0.9
Otitis externa									
Diabetes treatment group 1	3 (1.2)	3	0.9	0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	0		
Acute sinusitis									
Diabetes treatment group 1	3 (1.2)	3	0.9	1 (0.4)	1	0.3	3 (1.3)	5	1.6
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Localised infection									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Tooth infection									
Diabetes treatment group 1	2 (0.8)	3	0.9	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Abscess									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Chronic sinusitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Diverticulitis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	2 (1.2)	2	0.9
Infected dermal cyst									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Kidney infection									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Periodontitis									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Post procedural infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Urosepsis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Appendicitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Breast abscess									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Implant site infection									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Mastitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Otitis media acute									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Respiratory tract infection									

Adverse events with onset prior to randomisation are not included.
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.3)	3	1.0
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Rhinitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.3)	3	1.0
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Skin infection									
Diabetes treatment group 1	0			1 (0.4)	2	0.7	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Tooth abscess									
Diabetes treatment group 1	4 (1.6)	4	1.3	1 (0.4)	1	0.3	1 (0.4)	2	0.7
Diabetes treatment group 2	0			0			0		
Vulvovaginitis									
Diabetes treatment group 1	0			1 (0.4)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Colonic abscess									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Ear infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Empyema									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Eye infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Gingival abscess									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gingivitis									
Diabetes treatment group 1	0			0			3 (1.3)	3	1.0
Diabetes treatment group 2	0			0			0		
Hordeolum									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Joint abscess									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Labyrinthitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Laryngitis									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			0		
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Mastoiditis									
Diabetes treatment group 1	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Osteomyelitis									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Otitis media									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Otitis media chronic									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Pericoronitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Postoperative wound infection									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Pulpitis dental									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Pyelonephritis acute									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Sepsis									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Sialoadenitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Sinobronchitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Subcutaneous abscess									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Tracheitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Tracheobronchitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Vaginal infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Wound infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Viral infectious disorders									
Diabetes treatment group 1	19 (7.8)	22	6.9	21 (9.1)	23	7.5	20 (8.7)	22	7.3
Diabetes treatment group 2	16 (10.1)	19	8.9	15 (8.7)	18	8.0	16 (9.3)	20	8.9
Influenza									
Diabetes treatment group 1	7 (2.9)	8	2.5	7 (3.0)	7	2.3	11 (4.8)	12	4.0
Diabetes treatment group 2	10 (6.3)	11	5.2	8 (4.7)	9	4.0	7 (4.1)	10	4.4
Gastroenteritis viral									
Diabetes treatment group 1	3 (1.2)	3	0.9	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	4	1.8	4 (2.3)	4	1.8
Herpes zoster									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Viral infection									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	4	1.3	3 (1.3)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Herpes virus infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Oral herpes									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	2	0.9	1 (0.6)	1	0.4	0		
Gastroenteritis norovirus									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Herpes simplex									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ophthalmic herpes zoster									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Pneumonia influenzal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Respiratory tract infection viral									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Viral diarrhoea									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Viral pharyngitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Chikungunya virus infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Ear infection viral									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Rhinovirus infection									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Viral upper respiratory tract infection									
Diabetes treatment group 1	2 (0.8)	3	0.9	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Bacterial infectious disorders									
Diabetes treatment group 1	4 (1.6)	4	1.3	4 (1.7)	4	1.3	8 (3.5)	11	3.6
Diabetes treatment group 2	6 (3.8)	9	4.2	4 (2.3)	4	1.8	4 (2.3)	7	3.1
Cellulitis									
Diabetes treatment group 1	3 (1.2)	3	0.9	0			3 (1.3)	4	1.3
Diabetes treatment group 2	2 (1.3)	3	1.4	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Ear infection bacterial									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	3	1.4	1 (0.6)	1	0.4	0		
Furuncle									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	2	0.9
Bacterial vaginosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Breast cellulitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Pharyngitis streptococcal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	3 (1.3)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Staphylococcal infection									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	2	0.9
Clostridium difficile colitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Helicobacter gastritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Helicobacter infection									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Wound infection staphylococcal									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Fungal infectious disorders									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	5 (2.1)	5	1.6	5 (2.2)	5	1.6	10 (4.3)	11	3.6
Diabetes treatment group 2	9 (5.7)	9	4.2	2 (1.2)	2	0.9	5 (2.9)	6	2.7
Onychomycosis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Fungal infection									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Fungal skin infection									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Tinea pedis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Vulvovaginal candidiasis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	2	0.9
Vulvovaginal mycotic infection									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	3 (1.3)	3	1.0
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Balanitis candida									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Candida infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Dermatophytosis of nail									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Genital candidiasis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	2	(1.3)	2 0.9	0			0		
Genital infection fungal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Skin candida									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Tinea infection									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	1	(0.6)	1 0.5	0			1	(0.6)	1 0.4
Tinea versicolour									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Ectoparasitic disorders									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Acarodermatitis												
Diabetes treatment group 1	0				0				1	(0.4)	1	0.3
Diabetes treatment group 2	0				0				0			
Musculoskeletal and connective tissue disorders												
Diabetes treatment group 1	54	(22.2)	76	24.0	54	(23.4)	80	26.1	52	(22.6)	80	26.4
Diabetes treatment group 2	45	(28.3)	71	33.4	44	(25.6)	71	31.4	32	(18.6)	46	20.4
Musculoskeletal and connective tissue disorders NEC												
Diabetes treatment group 1	30	(12.3)	34	10.7	33	(14.3)	40	13.0	20	(8.7)	22	7.3
Diabetes treatment group 2	27	(17.0)	32	15.1	23	(13.4)	26	11.5	13	(7.6)	16	7.1
Back pain												
Diabetes treatment group 1	17	(7.0)	18	5.7	18	(7.8)	20	6.5	11	(4.8)	12	4.0
Diabetes treatment group 2	11	(6.9)	12	5.6	9	(5.2)	10	4.4	3	(1.7)	3	1.3
Pain in extremity												
Diabetes treatment group 1	5	(2.1)	5	1.6	8	(3.5)	8	2.6	4	(1.7)	4	1.3
Diabetes treatment group 2	7	(4.4)	7	3.3	8	(4.7)	8	3.5	6	(3.5)	6	2.7
Neck pain												
Diabetes treatment group 1	0				6	(2.6)	6	2.0	2	(0.9)	2	0.7
Diabetes treatment group 2	2	(1.3)	2	0.9	2	(1.2)	2	0.9	1	(0.6)	1	0.4
Musculoskeletal pain												

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	5 (2.1)	5	1.6	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	4 (2.3)	4	1.8	3 (1.7)	3	1.3
Muscle contracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Neck mass									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Flank pain									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	3 (1.9)	3	1.4	0			0		
Musculoskeletal chest pain									
Diabetes treatment group 1	4 (1.6)	5	1.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Rheumatic disorder									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Axillary mass									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Limb mass									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	2	0.9	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Musculoskeletal discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Musculoskeletal stiffness									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Plantar fasciitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Joint disorders									
Diabetes treatment group 1	20 (8.2)	24	7.6	20 (8.7)	26	8.5	29 (12.6)	35	11.5
Diabetes treatment group 2	18 (11.3)	22	10.4	24 (14.0)	31	13.7	12 (7.0)	14	6.2
Arthralgia									
Diabetes treatment group 1	12 (4.9)	13	4.1	13 (5.6)	17	5.5	16 (7.0)	16	5.3
Diabetes treatment group 2	12 (7.5)	14	6.6	10 (5.8)	12	5.3	4 (2.3)	4	1.8
Osteoarthritis									
Diabetes treatment group 1	2 (0.8)	2	0.6	6 (2.6)	7	2.3	7 (3.0)	8	2.6
Diabetes treatment group 2	0			5 (2.9)	7	3.1	5 (2.9)	5	2.2
Periarthritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	3 (1.9)	3	1.4	3 (1.7)	5	2.2	1 (0.6)	1	0.4
Rotator cuff syndrome									
Diabetes treatment group 1	4 (1.6)	6	1.9	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	4	1.8	0		
Spinal osteoarthritis									
Diabetes treatment group 1	0			0			4 (1.7)	4	1.3
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Arthritis									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Joint swelling									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Arthritis climacteric									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Arthropathy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Femoroacetabular impingement									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gouty arthritis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Joint effusion									

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Neuropathic arthropathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Psoriatic arthropathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Rheumatoid arthritis									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	0			0			0		
Sacroiliitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Muscle disorders									
Diabetes treatment group 1	8 (3.3)	10	3.2	4 (1.7)	4	1.3	6 (2.6)	6	2.0
Diabetes treatment group 2	4 (2.5)	6	2.8	6 (3.5)	8	3.5	2 (1.2)	3	1.3
Muscle spasms									
Diabetes treatment group 1	5 (2.1)	6	1.9	2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	0		
Myalgia									
Diabetes treatment group 1	3 (1.2)	4	1.3	2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	3 (1.9)	4	1.9	3 (1.7)	5	2.2	2 (1.2)	3	1.3

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diastasis recti abdominis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Muscular weakness									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Tendon, ligament and cartilage disorders									
Diabetes treatment group 1	3 (1.2)	3	0.9	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	2 (1.2)	2	0.9	6 (3.5)	7	3.1
Trigger finger									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Tendonitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	5 (2.9)	5	2.2
Osteochondrosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Tendon disorder									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Costochondritis									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Ligament calcification									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Meniscal degeneration									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Tendon pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Synovial and bursal disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	3 (1.3)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Bursitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	3 (1.3)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Bone disorders (excl congenital and fractures)									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	2	0.7	3 (1.3)	3	1.0
Diabetes treatment group 2	4 (2.5)	4	1.9	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Exostosis									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Osteoporosis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Bone lesion									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Osteopenia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Bone pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Metatarsalgia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Osteitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	5 (2.2)	6	2.0

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	3 (1.9)	3	1.4	0			3 (1.7)	3	1.3
Intervertebral disc protrusion									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	2	0.9
Foot deformity									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Intervertebral disc degeneration									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Scoliosis									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Spinal flattening									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Spondylolisthesis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Connective tissue disorders (excl congenital)									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Polymyalgia rheumatica									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Nervous system disorders									
Diabetes treatment group 1	35 (14.4)	61	19.2	44 (19.0)	65	21.2	41 (17.8)	64	21.1
Diabetes treatment group 2	28 (17.6)	44	20.7	38 (22.1)	53	23.4	22 (12.8)	28	12.4
Neurological disorders NEC									
Diabetes treatment group 1	15 (6.2)	17	5.4	20 (8.7)	27	8.8	23 (10.0)	28	9.2
Diabetes treatment group 2	13 (8.2)	16	7.5	16 (9.3)	19	8.4	8 (4.7)	10	4.4
Dizziness									
Diabetes treatment group 1	9 (3.7)	10	3.2	13 (5.6)	14	4.6	10 (4.3)	12	4.0
Diabetes treatment group 2	9 (5.7)	11	5.2	6 (3.5)	6	2.7	3 (1.7)	3	1.3
Paraesthesia									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	4 (1.7)	5	1.6
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	5	2.2	2 (1.2)	2	0.9
Dysgeusia									
Diabetes treatment group 1	0			2 (0.9)	6	2.0	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	1	0.4
Hypoaesthesia									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			3 (1.7)	3	1.3	0		
Hyperaesthesia									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Dizziness postural									
Diabetes treatment group 1	1 (0.4)	2	0.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Somnolence									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Syncope									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Ageusia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Aphasia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Coordination abnormal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Dysaesthesia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Head discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Hypogeusia									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Lethargy									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Loss of consciousness									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Neuralgia									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Phantom limb syndrome									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Presyncope									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Restless legs syndrome									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Headaches									
Diabetes treatment group 1	19 (7.8)	34	10.7	24 (10.4)	30	9.8	16 (7.0)	23	7.6
Diabetes treatment group 2	17 (10.7)	22	10.4	13 (7.6)	16	7.1	8 (4.7)	9	4.0
Headache									
Diabetes treatment group 1	17 (7.0)	29	9.1	21 (9.1)	27	8.8	15 (6.5)	21	6.9
Diabetes treatment group 2	16 (10.1)	19	8.9	10 (5.8)	13	5.7	5 (2.9)	6	2.7
Migraine									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	0			3 (1.7)	3	1.3	0		
Migraine with aura									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Tension headache									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	3 (1.9)	3	1.4	0			1 (0.6)	1	0.4
Occipital neuralgia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Sinus headache									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Central nervous system vascular disorders									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	1 (0.4)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	5 (2.9)	8	3.5	1 (0.6)	1	0.4
Carotid artery stenosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	0		
Carotid arteriosclerosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cerebrovascular accident									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Cerebral artery thrombosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cerebral infarction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Spinal epidural haematoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Subarachnoid haemorrhage									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cerebral artery stenosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ischaemic stroke									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Peripheral neuropathies									
Diabetes treatment group 1	4 (1.6)	5	1.6	0			4 (1.7)	5	1.6
Diabetes treatment group 2	2 (1.3)	2	0.9	4 (2.3)	4	1.8	3 (1.7)	3	1.3
Carpal tunnel syndrome									
Diabetes treatment group 1	3 (1.2)	4	1.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Diabetic neuropathy									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Meralgia paraesthetica									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Neuropathy peripheral									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nerve compression									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Polyneuropathy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Spinal cord and nerve root disorders									
Diabetes treatment group 1	4 (1.6)	4	1.3	0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	4	1.8	2 (1.2)	2	0.9
Sciatica									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Radiculopathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Sacral radiculopathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cervical radiculopathy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Cervicobrachial syndrome									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Lumbar radiculopathy									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Cranial nerve disorders (excl neoplasms)									
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			1	(0.6)	1 0.4	0		
Facial paralysis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(0.6)	1 0.4	0		
Anosmia									
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			0			0		
Encephalopathies									
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			1	(0.6)	1 0.4	0		
Hyponatraemic encephalopathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(0.6)	1 0.4	0		
Hepatic encephalopathy									
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Mental impairment disorders									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	2	0.9
Memory impairment									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Amnesia									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Dementia Alzheimer's type									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Vascular dementia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Sleep disturbances (incl subtypes)									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Hypersomnia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Structural brain disorders									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Cerebral ventricle dilatation									
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			0			0		
Movement disorders (incl parkinsonism)									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Tremor									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Neurological disorders of the eye									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Visual field defect									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Seizures (incl subtypes)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Partial seizures									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
General disorders and administration site conditions									
Diabetes treatment group 1	27 (11.1)	38	12.0	44 (19.0)	62	20.2	28 (12.2)	33	10.9
Diabetes treatment group 2	24 (15.1)	31	14.6	25 (14.5)	31	13.7	18 (10.5)	28	12.4
General system disorders NEC									
Diabetes treatment group 1	25 (10.3)	34	10.7	36 (15.6)	45	14.7	16 (7.0)	16	5.3
Diabetes treatment group 2	15 (9.4)	18	8.5	21 (12.2)	23	10.2	12 (7.0)	14	6.2
Fatigue									
Diabetes treatment group 1	11 (4.5)	18	5.7	17 (7.4)	18	5.9	4 (1.7)	4	1.3
Diabetes treatment group 2	8 (5.0)	8	3.8	11 (6.4)	11	4.9	0		
Asthenia									
Diabetes treatment group 1	3 (1.2)	3	0.9	5 (2.2)	6	2.0	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Influenza like illness									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	4	1.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	2 (1.2)	2	0.9
Malaise									
Diabetes treatment group 1	1 (0.4)	2	0.6	3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Early satiety									
Diabetes treatment group 1	2 (0.8)	2	0.6	4 (1.7)	4	1.3	1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	0			1 (0.6)	1	0.4
Non-cardiac chest pain									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Pain									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	3 (1.9)	3	1.4	1 (0.6)	1	0.4	2 (1.2)	2	0.9
Peripheral swelling									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	2	0.9
Oedema peripheral									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	2	0.9
Chest discomfort									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hunger									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Swelling									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Chest pain									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	3	1.3

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Face oedema									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Feeling cold									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Thirst decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Chills									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Inflammation									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Polyp									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	2	0.9	0			0		
Sensation of foreign body									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Thirst									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	0			0			0		
Administration site reactions									
Diabetes treatment group 1	1 (0.4)	2	0.6	9 (3.9)	13	4.2	7 (3.0)	8	2.6
Diabetes treatment group 2	5 (3.1)	5	2.4	4 (2.3)	6	2.7	3 (1.7)	10	4.4
Injection site pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	4 (1.7)	4	1.3	0		
Diabetes treatment group 2	3 (1.9)	3	1.4	3 (1.7)	5	2.2	3 (1.7)	7	3.1
Injection site erythema									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Injection site bruising									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	3 (1.3)	3	1.0
Diabetes treatment group 2	2 (1.3)	2	0.9	0			2 (1.2)	3	1.3
Injection site reaction									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Implant site pain									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Injection site mass									

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Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Injection site discomfort									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Injection site haemorrhage									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Injection site urticaria									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Body temperature conditions									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	6 (2.6)	9	3.0
Diabetes treatment group 2	7 (4.4)	7	3.3	2 (1.2)	2	0.9	3 (1.7)	3	1.3
Pyrexia									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	6 (2.6)	9	3.0
Diabetes treatment group 2	7 (4.4)	7	3.3	2 (1.2)	2	0.9	3 (1.7)	3	1.3
Therapeutic and nontherapeutic effects (excl toxicity)									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Drug intolerance									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Tissue disorders NEC									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Mass									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Nodule									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Complications associated with device									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Complication associated with device									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Metabolism and nutrition disorders									
Diabetes treatment group 1	23 (9.5)	32	10.1	28 (12.1)	32	10.4	35 (15.2)	41	13.5
Diabetes treatment group 2	25 (15.7)	36	16.9	28 (16.3)	34	15.0	18 (10.5)	20	8.9
Appetite and general nutritional disorders									
Diabetes treatment group 1	15 (6.2)	17	5.4	19 (8.2)	22	7.2	13 (5.7)	15	4.9

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	17 (10.7)	23	10.8	22 (12.8)	24	10.6	3 (1.7)	3	1.3
Decreased appetite									
Diabetes treatment group 1	13 (5.3)	15	4.7	16 (6.9)	18	5.9	13 (5.7)	15	4.9
Diabetes treatment group 2	16 (10.1)	19	8.9	22 (12.8)	23	10.2	2 (1.2)	2	0.9
Hyperphagia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Increased appetite									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	2 (1.3)	3	1.4	0			0		
Overweight									
Diabetes treatment group 1	0			1 (0.4)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Cachexia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Obesity									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Electrolyte and fluid balance conditions									
Diabetes treatment group 1	3 (1.2)	3	0.9	4 (1.7)	4	1.3	2 (0.9)	2	0.7
Diabetes treatment group 2	3 (1.9)	4	1.9	3 (1.7)	3	1.3	1 (0.6)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dehydration									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	0		
Hypokalaemia									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	0		
Diabetes treatment group 2	2 (1.3)	3	1.4	0			0		
Hyponatraemia									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Hyperkalaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Lipid metabolism disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	6 (2.6)	6	2.0
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	3 (1.7)	3	1.3
Dyslipidaemia									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	5 (2.2)	5	1.6
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hyperlipidaemia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Hypertriglyceridaemia									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Hypercholesterolaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Purine and pyrimidine metabolism disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	3 (1.3)	5	1.6
Diabetes treatment group 2	2 (1.3)	3	1.4	1 (0.6)	1	0.4	0		
Gout									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	4	1.3
Diabetes treatment group 2	2 (1.3)	3	1.4	1 (0.6)	1	0.4	0		
Hyperuricaemia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Vitamin related disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Vitamin B complex deficiency									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Folate deficiency									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vitamin D deficiency									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Acid-base disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Ketoacidosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Lactic acidosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Bone, calcium, magnesium and phosphorus metabolism disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	1 (0.6)	1	0.4	3 (1.7)	3	1.3
Hypomagnesaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Hypercalcaemia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	2	0.9
Hypercalcitoninaemia									

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hypocalcaemia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Diabetic complications									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Diabetic ketoacidosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Diabetic metabolic decompensation									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Glucose metabolism disorders (incl diabetes mellitus)									
Diabetes treatment group 1	2 (0.8)	3	0.9	1 (0.4)	1	0.3	11 (4.8)	11	3.6
Diabetes treatment group 2	1 (0.6)	1	0.5	0			9 (5.2)	9	4.0
Diabetes mellitus									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	4 (1.7)	4	1.3
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Diabetes mellitus inadequate control									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			4 (1.7)	4	1.3

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Hyperglycaemia									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	1	(0.6)	1 0.5	0			3	(1.7)	3 1.3
Hyperinsulinaemia									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Hypoglycaemia									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Type 2 diabetes mellitus									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			3	(1.7)	3 1.3
Iron and trace metal metabolism disorders									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Iron deficiency									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Metabolism disorders NEC									
Diabetes treatment group 1	1	(0.4)	2 0.6	0			0		
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hyperamylasaemia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Hyperlipasaemia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Eye disorders									
Diabetes treatment group 1	28 (11.5)	39	12.3	27 (11.7)	33	10.8	24 (10.4)	35	11.5
Diabetes treatment group 2	18 (11.3)	26	12.2	23 (13.4)	36	15.9	18 (10.5)	21	9.3
Retina, choroid and vitreous haemorrhages and vascular disorders									
Diabetes treatment group 1	7 (2.9)	8	2.5	12 (5.2)	13	4.2	4 (1.7)	5	1.6
Diabetes treatment group 2	5 (3.1)	5	2.4	9 (5.2)	10	4.4	7 (4.1)	7	3.1
Diabetic retinopathy									
Diabetes treatment group 1	7 (2.9)	8	2.5	9 (3.9)	10	3.3	4 (1.7)	5	1.6
Diabetes treatment group 2	4 (2.5)	4	1.9	6 (3.5)	6	2.7	7 (4.1)	7	3.1
Non-proliferative retinopathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Retinal haemorrhage									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retinopathy hypertensive									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Retinal artery occlusion									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Retinopathy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Anterior eye structural change, deposit and degeneration									
Diabetes treatment group 1	3 (1.2)	3	0.9	4 (1.7)	5	1.6	7 (3.0)	9	3.0
Diabetes treatment group 2	5 (3.1)	5	2.4	5 (2.9)	6	2.7	5 (2.9)	6	2.7
Cataract									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	3	1.0	4 (1.7)	4	1.3
Diabetes treatment group 2	3 (1.9)	3	1.4	3 (1.7)	3	1.3	4 (2.3)	5	2.2
Dermatochalasis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Narrow anterior chamber angle									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Cataract cortical									

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Cataract subcapsular									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Cataract nuclear									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Pinguecula									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Posterior capsule opacification									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Ocular infections, irritations and inflammations									
Diabetes treatment group 1	9 (3.7)	9	2.8	1 (0.4)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	4 (2.5)	4	1.9	7 (4.1)	8	3.5	2 (1.2)	2	0.9
Macular oedema									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	3	1.3	0		
Blepharitis									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	2	0.7	2 (0.9)	2	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Eyelid rash									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Keratitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Meibomian gland dysfunction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Ocular hyperaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	2	0.9
Conjunctivitis allergic									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Episcleritis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Eye pruritus									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Punctate keratitis									

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Swelling of eyelid									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Uveitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Eye disorders NEC									
Diabetes treatment group 1	6 (2.5)	6	1.9	5 (2.2)	5	1.6	5 (2.2)	5	1.6
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	2 (1.2)	2	0.9
Dry eye									
Diabetes treatment group 1	3 (1.2)	3	0.9	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	2 (1.2)	2	0.9
Lacrimation increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Vitreous disorder									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Eyelid disorder									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Retinal disorder									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Diabetes treatment group 1	6 (2.5)	7	2.2	3 (1.3)	3	1.0	3 (1.3)	4	1.3
Diabetes treatment group 2	4 (2.5)	5	2.4	3 (1.7)	3	1.3	0		
Detachment of retinal pigment epithelium									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Macular fibrosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	2	0.9	1 (0.6)	1	0.4	0		
Optic disc disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Retinal degeneration									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Retinal depigmentation									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vitreous detachment									
Diabetes treatment group 1	1 (0.4)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Age-related macular degeneration									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	0			0			0		
Choroidal dystrophy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Macular degeneration									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Optic atrophy									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Retinal drusen									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Vitreous floaters									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Vision disorders									
Diabetes treatment group 1	4 (1.6)	4	1.3	3 (1.3)	3	1.0	5 (2.2)	5	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	4 (2.5)	4	1.9	2 (1.2)	2	0.9	3 (1.7)	3	1.3
Vision blurred									
Diabetes treatment group 1	3 (1.2)	3	0.9	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	2 (1.2)	2	0.9
Visual impairment									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Myopia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Astigmatism									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hypermetropia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Pathologic myopia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Presbyopia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Glaucoma and ocular hypertension									

Adverse events with onset prior to randomisation are not included.
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	1 (0.6)	1	0.4
Glaucoma									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	1 (0.6)	1	0.4
Ocular neuromuscular disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Eyelid ptosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Ocular sensory symptoms NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Asthenopia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Ocular haemorrhages and vascular disorders NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Eye haemorrhage									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Conjunctival haemorrhage									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Optic disc haemorrhage									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Injury, poisoning and procedural complications									
Diabetes treatment group 1	33 (13.6)	44	13.9	27 (11.7)	36	11.7	31 (13.5)	37	12.2
Diabetes treatment group 2	18 (11.3)	27	12.7	21 (12.2)	32	14.1	18 (10.5)	24	10.7
Injuries NEC									
Diabetes treatment group 1	25 (10.3)	31	9.8	16 (6.9)	20	6.5	20 (8.7)	21	6.9
Diabetes treatment group 2	12 (7.5)	18	8.5	16 (9.3)	19	8.4	16 (9.3)	19	8.4
Muscle strain									
Diabetes treatment group 1	4 (1.6)	4	1.3	6 (2.6)	6	2.0	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Fall									
Diabetes treatment group 1	5 (2.1)	5	1.6	4 (1.7)	5	1.6	1 (0.4)	1	0.3
Diabetes treatment group 2	3 (1.9)	3	1.4	1 (0.6)	1	0.4	1 (0.6)	2	0.9
Limb injury									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	0		
Skin laceration									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	1 (0.6)	1	0.4
Ligament sprain									
Diabetes treatment group 1	4 (1.6)	5	1.6	3 (1.3)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	3	1.4	0			4 (2.3)	4	1.8
Bone contusion									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Contusion									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	4 (1.7)	4	1.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	4 (2.3)	5	2.2
Animal bite									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Muscle injury									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Post-traumatic pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Road traffic accident									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Tooth fracture									
Diabetes treatment group 1	3 (1.2)	3	0.9	0			3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Traumatic haemothorax									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Arthropod sting									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Epicondylitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Face injury									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Head injury									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Skin abrasion									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Abdominal injury									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Arthropod bite									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Chest injury									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Craniocerebral injury									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Foreign body in eye									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Injury corneal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Ligament rupture									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Muscle rupture									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Post-traumatic neck syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			1	(0.6)	1 0.4
Soft tissue injury									
Diabetes treatment group 1	5	(2.1)	5 1.6	0			0		
Diabetes treatment group 2	0			0			0		
Spinal column injury									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Subdural haematoma									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Tendon injury									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Tendon rupture									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Wound									
Diabetes treatment group 1	0			0			3	(1.3)	3 1.0
Diabetes treatment group 2	0			0			0		
Bone and joint injuries									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	4 (1.6)	5	1.6	10 (4.3)	11	3.6	10 (4.3)	10	3.3
Diabetes treatment group 2	4 (2.5)	4	1.9	4 (2.3)	8	3.5	3 (1.7)	3	1.3
Rib fracture									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Foot fracture									
Diabetes treatment group 1	0			4 (1.7)	4	1.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Humerus fracture									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Cervical vertebral fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Joint injury									
Diabetes treatment group 1	0			0			4 (1.7)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Spinal compression fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Thoracic vertebral fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Upper limb fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Meniscus injury									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Radius fracture									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Stress fracture									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Wrist fracture									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ankle fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Bone fissure									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Cartilage injury									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Hand fracture									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Hip fracture									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Joint dislocation									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Lisfranc fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Spinal fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Sternal fracture									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Procedural related injuries and complications NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	4 (1.7)	4	1.3	4 (1.7)	4	1.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Post procedural haemorrhage									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Anaemia postoperative									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Graft complication									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Procedural pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Dental restoration failure									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Incision site pain									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Post procedural complication									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Surgical skin tear									
Diabetes treatment group 1	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Injuries by physical agents									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	0		
Hypobarism									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Sunburn									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Thermal burn									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Heat illness									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Medication errors and other product use errors and issues									
Diabetes treatment group 1	3 (1.2)	5	1.6	1 (0.4)	1	0.3	1 (0.4)	2	0.7
Diabetes treatment group 2	2 (1.3)	3	1.4	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Accidental overdose									
Diabetes treatment group 1	2 (0.8)	4	1.3	0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Extra dose administered									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Dose calculation error									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Incorrect dose administered									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	2	0.9	0			0		
Overdoses and underdoses NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Intentional overdose									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Diabetes treatment group 1	24 (9.9)	28	8.8	25 (10.8)	35	11.4	20 (8.7)	24	7.9
Diabetes treatment group 2	12 (7.5)	16	7.5	22 (12.8)	27	11.9	16 (9.3)	19	8.4
Respiratory tract signs and symptoms									
Diabetes treatment group 1	8 (3.3)	8	2.5	9 (3.9)	9	2.9	4 (1.7)	4	1.3
Diabetes treatment group 2	5 (3.1)	5	2.4	10 (5.8)	10	4.4	5 (2.9)	5	2.2

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Oropharyngeal pain									
Diabetes treatment group 1	6 (2.5)	6	1.9	2 (0.9)	2	0.7	3 (1.3)	3	1.0
Diabetes treatment group 2	2 (1.3)	2	0.9	5 (2.9)	5	2.2	3 (1.7)	3	1.3
Rhinorrhoea									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	2 (1.3)	2	0.9	1 (0.6)	1	0.4	0		
Dysphonia									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Aphonia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Dry throat									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hiccups									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Upper respiratory tract congestion									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Oropharyngeal discomfort									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Painful respiration									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Nasal discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Upper-airway cough syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Respiratory disorders NEC									
Diabetes treatment group 1	10 (4.1)	11	3.5	11 (4.8)	12	3.9	9 (3.9)	12	4.0
Diabetes treatment group 2	6 (3.8)	6	2.8	7 (4.1)	7	3.1	6 (3.5)	6	2.7
Cough									
Diabetes treatment group 1	6 (2.5)	7	2.2	5 (2.2)	5	1.6	5 (2.2)	6	2.0
Diabetes treatment group 2	4 (2.5)	4	1.9	4 (2.3)	4	1.8	2 (1.2)	2	0.9
Productive cough									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pulmonary mass									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Respiratory disorder									

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Acute respiratory failure									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Sleep apnoea syndrome									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Dyspnoea									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hypoxia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Upper respiratory tract disorders (excl infections)									
Diabetes treatment group 1	4 (1.6)	4	1.3	7 (3.0)	8	2.6	1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	3	1.4	3 (1.7)	4	1.8	7 (4.1)	8	3.6
Epistaxis									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	4 (2.3)	4	1.8
Rhinitis allergic									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Nasal congestion									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	2	0.9	1 (0.6)	1	0.4	2 (1.2)	3	1.3
Sinus congestion									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Bronchial disorders (excl neoplasms)									
Diabetes treatment group 1	5 (2.1)	5	1.6	3 (1.3)	5	1.6	6 (2.6)	6	2.0
Diabetes treatment group 2	0			4 (2.3)	4	1.8	0		
Asthma									
Diabetes treatment group 1	3 (1.2)	3	0.9	2 (0.9)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	0			3 (1.7)	3	1.3	0		
Bronchospasm									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Chronic obstructive pulmonary disease									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Childhood asthma									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lower respiratory tract disorders (excl obstruction and infection)									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	2	0.9	1 (0.6)	1	0.4	0		
Idiopathic interstitial pneumonia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Atelectasis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Emphysema									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Pleural disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pneumothorax									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Skin and subcutaneous tissue disorders									
Diabetes treatment group 1	22 (9.1)	26	8.2	21 (9.1)	31	10.1	20 (8.7)	22	7.3
Diabetes treatment group 2	16 (10.1)	17	8.0	19 (11.0)	23	10.2	17 (9.9)	20	8.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Epidermal and dermal conditions									
Diabetes treatment group 1	13 (5.3)	14	4.4	13 (5.6)	18	5.9	11 (4.8)	11	3.6
Diabetes treatment group 2	10 (6.3)	11	5.2	14 (8.1)	17	7.5	11 (6.4)	12	5.3
Rash									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	4	1.3	3 (1.3)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	5 (2.9)	6	2.7	1 (0.6)	1	0.4
Eczema									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	3 (1.9)	3	1.4	1 (0.6)	1	0.4	2 (1.2)	2	0.9
Dry skin									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Rash pruritic									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	2	0.9	2 (1.2)	2	0.9	0		
Blister									
Diabetes treatment group 1	0			1 (0.4)	2	0.7	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Drug eruption									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	3	1.3
Intertrigo									
Diabetes treatment group 1	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pain of skin									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Perioral dermatitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Sensitive skin									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Skin lesion									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Decubitus ulcer									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Dermatitis allergic									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Dermatitis contact									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Pruritus									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			3 (1.7)	3	1.3
Psoriasis									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Skin burning sensation									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Skin exfoliation									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Dermatitis									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Erythema									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			0		
Diabetes treatment group 2	0			0			0		
Neurodermatitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Parapsoriasis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Rash erythematous									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Stasis dermatitis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Xanthelasma									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Skin appendage conditions									
Diabetes treatment group 1	6 (2.5)	6	1.9	5 (2.2)	7	2.3	6 (2.6)	6	2.0
Diabetes treatment group 2	5 (3.1)	5	2.4	4 (2.3)	5	2.2	2 (1.2)	2	0.9
Alopecia									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	2 (0.9)	2	0.7
Diabetes treatment group 2	4 (2.5)	4	1.9	2 (1.2)	3	1.3	0		
Acne									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Alopecia areata									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hyperhidrosis									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	2	0.7	1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Ingrowing nail									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Onychomadesis									
Diabetes treatment group 1	0			1 (0.4)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Miliaria									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Nail dystrophy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Cutaneous neoplasms benign									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			2 (0.9)	3	1.0
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Dermal cyst									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			2 (0.9)	3	1.0
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Angioedema and urticaria									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Urticaria									

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Chronic spontaneous urticaria									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Cornification and dystrophic skin disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Actinic keratosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Dermatitis papillaris capillitii									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hyperkeratosis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Punctate keratosis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Skin and subcutaneous tissue disorders NEC									

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	4	1.3	0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Diabetic foot									
Diabetes treatment group 1	0			1 (0.4)	3	1.0	0		
Diabetes treatment group 2	0			0			0		
Skin ulcer									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Skin vascular abnormalities									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Ecchymosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Haemorrhage subcutaneous									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Investigations									
Diabetes treatment group 1	13 (5.3)	17	5.4	26 (11.3)	30	9.8	16 (7.0)	19	6.3
Diabetes treatment group 2	5 (3.1)	6	2.8	14 (8.1)	18	8.0	17 (9.9)	23	10.2
Cardiac and vascular investigations (excl enzyme tests)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	5 (2.9)	6	2.7	1 (0.6)	1	0.4
Heart rate increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Blood pressure increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cardiac murmur									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Cardiac stress test abnormal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Carotid pulse decreased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Electrocardiogram Q waves									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Electrocardiogram QT prolonged									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Blood pressure decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Electrocardiogram PR prolongation									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Electrocardiogram ST-T segment abnormal									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Gastrointestinal investigations									
Diabetes treatment group 1	5 (2.1)	5	1.6	4 (1.7)	4	1.3	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	3 (1.7)	4	1.8
Lipase increased									
Diabetes treatment group 1	4 (1.6)	4	1.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	2 (1.2)	2	0.9
Colonoscopy normal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Occult blood									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Occult blood positive									

Adverse events with onset prior to randomisation are not included.
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Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			1	(0.4)	1 0.3	0		
Diabetes treatment group 2	0			0			0		
Amylase increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Faecal volume increased									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Pancreatic enzymes increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Renal and urinary tract investigations and urinalyses									
Diabetes treatment group 1	0			6	(2.6)	6 2.0	0		
Diabetes treatment group 2	0			0			0		
Glomerular filtration rate decreased									
Diabetes treatment group 1	0			3	(1.3)	3 1.0	0		
Diabetes treatment group 2	0			0			0		
Urine albumin/creatinine ratio increased									
Diabetes treatment group 1	0			2	(0.9)	2 0.7	0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urine albumin/creatinine ratio abnormal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Haematology investigations (incl blood groups)									
Diabetes treatment group 1	0			2 (0.9)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	3	1.3	0		
Haemoglobin decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Haematocrit decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Platelet count decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Endocrine investigations (incl sex hormones)									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Blood thyroid stimulating hormone increased									

Adverse events with onset prior to randomisation are not included.
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SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Blood thyroid stimulating hormone decreased									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Blood parathyroid hormone increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Hepatobiliary investigations									
Diabetes treatment group 1	1 (0.4)	2	0.6	1 (0.4)	1	0.3	4 (1.7)	6	2.0
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	3 (1.7)	4	1.8
Liver function test abnormal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Liver function test increased									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hepatic enzyme increased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Alanine aminotransferase increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			3 (1.3)	3	1.0

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Aspartate aminotransferase increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Blood bilirubin increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Transaminases increased									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Enzyme investigations NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Blood creatine phosphokinase increased									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Lipid analyses									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Lipids abnormal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Low density lipoprotein increased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Blood cholesterol increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Blood triglycerides increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Investigations, imaging and histopathology procedures NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Endoscopy abnormal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Neurological, special senses and psychiatric investigations									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Intraocular pressure increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Protein and chemistry analyses NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	3 (1.7)	3	1.3
C-reactive protein increased									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	3 (1.7)	3	1.3
Metabolic, nutritional and blood gas investigations									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	6 (2.6)	6	2.0
Diabetes treatment group 2	1 (0.6)	1	0.5	0			2 (1.2)	3	1.3
Vitamin B12 decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Blood glucose decreased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Blood glucose increased									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Blood uric acid increased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Brain natriuretic peptide increased									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Glycosylated haemoglobin increased									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Microbiology and serology investigations									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Helicobacter test positive									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Physical examination and organ system status topics									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Weight decreased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Weight increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Reproductive organ and breast investigations (excl hormone analyses)									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Mammogram abnormal									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Water, electrolyte and mineral investigations									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Blood potassium increased									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Blood potassium decreased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Blood sodium increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Cytogenetic investigations									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Prostatic specific antigen increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Immunology and allergy investigations									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Antinuclear antibody increased									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Renal and urinary disorders									
Diabetes treatment group 1	12 (4.9)	14	4.4	14 (6.1)	17	5.5	20 (8.7)	25	8.2
Diabetes treatment group 2	7 (4.4)	8	3.8	17 (9.9)	20	8.8	8 (4.7)	9	4.0
Urinary tract signs and symptoms									
Diabetes treatment group 1	7 (2.9)	7	2.2	7 (3.0)	7	2.3	15 (6.5)	18	5.9
Diabetes treatment group 2	0			10 (5.8)	10	4.4	1 (0.6)	1	0.4
Microalbuminuria									
Diabetes treatment group 1	3 (1.2)	3	0.9	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			3 (1.7)	3	1.3	0		
Dysuria									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	4 (1.7)	4	1.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Haematuria									

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	1	0.4
Nocturia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Proteinuria									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Renal colic									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pollakiuria									
Diabetes treatment group 1	3 (1.2)	3	0.9	1 (0.4)	1	0.3	3 (1.3)	3	1.0
Diabetes treatment group 2	0			0			0		
Lower urinary tract symptoms									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Micturition disorder									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	0			0			0		
Polyuria									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Urethral pain									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Urinary incontinence									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Nephropathies									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	1 (0.6)	1	0.4
Diabetic nephropathy									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Nephropathy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Renal disorders (excl nephropathies)									
Diabetes treatment group 1	4 (1.6)	4	1.3	3 (1.3)	5	1.6	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	3 (1.7)	3	1.3	4 (2.3)	4	1.8
Acute kidney injury									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Renal cyst									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			2 (1.2)	2	0.9	2 (1.2)	2	0.9
Chronic kidney disease									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Renal impairment									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Hydronephrosis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Kidney fibrosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Urolithiases									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	4 (1.7)	4	1.3
Diabetes treatment group 2	5 (3.1)	6	2.8	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Nephrolithiasis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			2 (0.9)	2	0.7
Diabetes treatment group 2	5 (3.1)	6	2.8	2 (1.2)	2	0.9	2 (1.2)	2	0.9
Calculus urinary									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Stag horn calculus									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ureterolithiasis									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			0		
Bladder and bladder neck disorders (excl calculi)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	1	0.4
Bladder outlet obstruction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hypertonic bladder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Bladder hypertrophy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Psychiatric disorders									
Diabetes treatment group 1	15 (6.2)	20	6.3	13 (5.6)	16	5.2	10 (4.3)	11	3.6
Diabetes treatment group 2	8 (5.0)	8	3.8	11 (6.4)	13	5.7	5 (2.9)	5	2.2
Sleep disorders and disturbances									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	3 (1.2)	3	0.9	6 (2.6)	6	2.0	3 (1.3)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	4 (2.3)	4	1.8	1 (0.6)	1	0.4
Insomnia									
Diabetes treatment group 1	3 (1.2)	3	0.9	3 (1.3)	3	1.0	3 (1.3)	3	1.0
Diabetes treatment group 2	3 (1.9)	3	1.4	4 (2.3)	4	1.8	1 (0.6)	1	0.4
Abnormal dreams									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Middle insomnia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Sleep disorder									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Depressed mood disorders and disturbances									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	3 (1.9)	3	1.4	4 (2.3)	4	1.8	3 (1.7)	3	1.3
Depressed mood									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	0		
Depression									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	2 (0.9)	2	0.7

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	3 (1.7)	3	1.3
Anhedonia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Major depression									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Anxiety disorders and symptoms									
Diabetes treatment group 1	8 (3.3)	9	2.8	2 (0.9)	2	0.7	5 (2.2)	5	1.6
Diabetes treatment group 2	2 (1.3)	2	0.9	3 (1.7)	3	1.3	1 (0.6)	1	0.4
Anxiety									
Diabetes treatment group 1	5 (2.1)	6	1.9	1 (0.4)	1	0.3	4 (1.7)	4	1.3
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	0		
Stress									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Anxiety disorder due to a general medical condition									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Generalised anxiety disorder									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nervousness									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	0			0			0		
Post-traumatic stress disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Mood disorders and disturbances NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Mood altered									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Irritability									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Mood swings									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Adjustment disorders (incl subtypes)									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Adjustment disorder with depressed mood									

Adverse events with onset prior to randomisation are not included.
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Grief reaction									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Changes in physical activity									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Restlessness									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Suicidal and self-injurious behaviours NEC									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Suicidal ideation									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Psychiatric disorders NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Mental status changes									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Sexual dysfunctions, disturbances and gender identity disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Libido decreased									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Vascular disorders									
Diabetes treatment group 1	13 (5.3)	13	4.1	15 (6.5)	16	5.2	21 (9.1)	23	7.6
Diabetes treatment group 2	9 (5.7)	10	4.7	9 (5.2)	10	4.4	9 (5.2)	9	4.0
Vascular hypertensive disorders									
Diabetes treatment group 1	7 (2.9)	7	2.2	8 (3.5)	9	2.9	10 (4.3)	11	3.6
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	5 (2.9)	5	2.2
Hypertension									
Diabetes treatment group 1	7 (2.9)	7	2.2	8 (3.5)	9	2.9	8 (3.5)	8	2.6
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	4 (2.3)	4	1.8
Hypertensive crisis									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hypertensive urgency									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Decreased and nonspecific blood pressure disorders and shock									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	3 (1.9)	4	1.9	3 (1.7)	4	1.8	2 (1.2)	2	0.9
Hypotension									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	3	1.4	1 (0.6)	1	0.4	0		
Blood pressure inadequately controlled									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Orthostatic hypotension									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	1 (0.6)	1	0.4
Shock									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Vascular disorders NEC									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Aortic rupture									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hot flush									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Aortic dilatation									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Vascular haemorrhagic disorders									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Haematoma									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
Diabetes treatment group 1	3 (1.2)	3	0.9	0			4 (1.7)	5	1.6
Diabetes treatment group 2	3 (1.9)	3	1.4	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Aortic arteriosclerosis									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Arteriosclerosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Peripheral arterial occlusive disease									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Peripheral artery stenosis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Peripheral coldness									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Peripheral venous disease									
Diabetes treatment group 1	0			0			2 (0.9)	3	1.0
Diabetes treatment group 2	0			0			0		
Vascular infections and inflammations									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Temporal arteritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Aneurysms and artery dissections									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Aortic aneurysm									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Embolism and thrombosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Post thrombotic syndrome									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Deep vein thrombosis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Lymphatic vessel disorders									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Lymphoedema									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Venous varices									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Varicose vein									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cardiac disorders									
Diabetes treatment group 1	9 (3.7)	9	2.8	11 (4.8)	15	4.9	6 (2.6)	9	3.0
Diabetes treatment group 2	11 (6.9)	15	7.1	11 (6.4)	13	5.7	7 (4.1)	8	3.6
Cardiac arrhythmias									
Diabetes treatment group 1	4 (1.6)	4	1.3	8 (3.5)	11	3.6	3 (1.3)	4	1.3
Diabetes treatment group 2	6 (3.8)	8	3.8	5 (2.9)	5	2.2	1 (0.6)	1	0.4
Atrial fibrillation									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Supraventricular extrasystoles									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	0		
Tachycardia									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	0		
Diabetes treatment group 2	0			0			0		
Bundle branch block right									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Atrioventricular block first degree									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Sinus tachycardia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Supraventricular tachycardia									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ventricular extrasystoles									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Atrial flutter									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	0			0			0		
Bradycardia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Bundle branch block left									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Coronary artery disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	5 (3.1)	5	2.4	4 (2.3)	4	1.8	3 (1.7)	3	1.3
Angina pectoris									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	1	0.4
Acute myocardial infarction									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Myocardial ischaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Angina unstable									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Coronary artery disease									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Myocardial infarction									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Arteriosclerosis coronary artery									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Cardiac disorders, signs and symptoms NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	3	1.3	2 (1.2)	2	0.9
Palpitations									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3

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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Cardiovascular disorder									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	2	0.9	0		
Hypertensive heart disease									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Heart failures									
Diabetes treatment group 1	0			0			1 (0.4)	2	0.7
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Cardiac failure congestive									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Cardiac failure acute									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Left ventricular failure									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Myocardial disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Cardiac hypertrophy									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Left ventricular hypertrophy									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Ear and labyrinth disorders									
Diabetes treatment group 1	5 (2.1)	6	1.9	12 (5.2)	12	3.9	7 (3.0)	9	3.0
Diabetes treatment group 2	6 (3.8)	8	3.8	8 (4.7)	8	3.5	5 (2.9)	5	2.2
Inner ear and VIIIth cranial nerve disorders									
Diabetes treatment group 1	4 (1.6)	5	1.6	5 (2.2)	5	1.6	7 (3.0)	8	2.6
Diabetes treatment group 2	4 (2.5)	6	2.8	5 (2.9)	5	2.2	1 (0.6)	1	0.4
Vertigo									
Diabetes treatment group 1	1 (0.4)	2	0.6	2 (0.9)	2	0.7	6 (2.6)	7	2.3
Diabetes treatment group 2	2 (1.3)	3	1.4	5 (2.9)	5	2.2	0		
Vertigo positional									
Diabetes treatment group 1	0			3 (1.3)	3	1.0	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Motion sickness									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	1 (0.6)	2	0.9	0			0		
Tinnitus									

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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	2 (0.8)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Aural disorders NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	4 (1.7)	4	1.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	2 (1.2)	2	0.9
Ear pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	3 (1.3)	3	1.0	1 (0.4)	1	0.3
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	1	0.4
Ear pruritus									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Ear discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hearing disorders									
Diabetes treatment group 1	0			2 (0.9)	2	0.7	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	1 (0.6)	1	0.4
Hypoacusis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Deafness bilateral									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		

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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Deafness unilateral									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Mixed deafness									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
External ear disorders (excl congenital)									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Cerumen impaction									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Excessive cerumen production									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Blood and lymphatic system disorders									
Diabetes treatment group 1	3 (1.2)	3	0.9	6 (2.6)	6	2.0	6 (2.6)	6	2.0
Diabetes treatment group 2	6 (3.8)	6	2.8	6 (3.5)	7	3.1	4 (2.3)	5	2.2
Anaemias nonhaemolytic and marrow depression									
Diabetes treatment group 1	3 (1.2)	3	0.9	5 (2.2)	5	1.6	4 (1.7)	4	1.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	5 (3.1)	5	2.4	5 (2.9)	6	2.7	2 (1.2)	2	0.9
Anaemia									
Diabetes treatment group 1	2 (0.8)	2	0.6	5 (2.2)	5	1.6	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	4 (2.3)	4	1.8	2 (1.2)	2	0.9
Iron deficiency anaemia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Pancytopenia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Hypochromic anaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Microcytic anaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Normocytic anaemia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Platelet disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Thrombocytosis									

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Spleen, lymphatic and reticuloendothelial system disorders									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Splenomegaly									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Lymphadenopathy									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
White blood cell disorders									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	0			1 (0.6)	1	0.4
Leukocytosis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Lymphopenia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Reproductive system and breast disorders									
Diabetes treatment group 1	11 (4.5)	15	4.7	6 (2.6)	6	2.0	8 (3.5)	9	3.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	4 (2.5)	5	2.4	6 (3.5)	6	2.7	1 (0.6)	2	0.9
Menstrual cycle and uterine bleeding disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			2 (1.2)	2	0.9	1 (0.6)	2	0.9
Metrorrhagia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Oligomenorrhoea									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Dysmenorrhoea									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Menorrhagia									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Menstruation irregular									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			1 (0.6)	2	0.9
Vulvovaginal disorders (excl infections and inflammations)									
Diabetes treatment group 1	1 (0.4)	1	0.3	2 (0.9)	2	0.7	2 (0.9)	2	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Vulval disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Vulva cyst									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Vulvovaginal pruritus									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Vaginal disorder									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Vaginal haemorrhage									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Vulvovaginal dryness									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Sexual function and fertility disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Erectile dysfunction									
Diabetes treatment group 1	2 (0.8)	2	0.6	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Breast disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Breast mass									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Breast cyst									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Breast pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Reproductive tract disorders NEC									
Diabetes treatment group 1	2 (0.8)	2	0.6	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pruritus genital									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Pelvic pain									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Menopause related conditions									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Atrophic vulvovaginitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Uterine, pelvic and broad ligament disorders									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Uterine polyp									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Adenomyosis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Endometriosis									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Male reproductive tract infections and inflammations									
Diabetes treatment group 1	4 (1.6)	4	1.3	0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Balanoposthitis									
Diabetes treatment group 1	3	(1.2)	3 0.9	0			0		
Diabetes treatment group 2	0			0			0		
Prostatitis									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Ovarian and fallopian tube disorders									
Diabetes treatment group 1	2	(0.8)	2 0.6	0			0		
Diabetes treatment group 2	0			0			0		
Haemorrhagic ovarian cyst									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Ovarian cyst									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Penile and scrotal disorders (excl infections and inflammations)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	2 0.9	0			0		
Penile erosion									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Peyronie's disease									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Prostatic disorders (excl infections and inflammations)									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Benign prostatic hyperplasia									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Testicular and epididymal disorders									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Testicular disorder									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Diabetes treatment group 1	5 (2.1)	7	2.2	4 (1.7)	5	1.6	7 (3.0)	9	3.0
Diabetes treatment group 2	8 (5.0)	9	4.2	5 (2.9)	5	2.2	5 (2.9)	5	2.2
Gastrointestinal neoplasms benign									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			1 (0.4)	1	0.3

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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	2 (1.3)	2	0.9	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Benign duodenal neoplasm									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Gastrointestinal tract adenoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Colon adenoma									
Diabetes treatment group 1	1 (0.4)	2	0.6	0			1 (0.4)	1	0.3
Diabetes treatment group 2	2 (1.3)	2	0.9	0			1 (0.6)	1	0.4
Leukaemias									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Myeloid leukaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Chronic lymphocytic leukaemia									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Cutaneous neoplasms benign									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Anogenital warts									

Adverse events with onset prior to randomisation are not included.
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Melanocytic naevus									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Soft tissue neoplasms benign									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Lipoma									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Lymphomas non-Hodgkin's unspecified histology									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal lymphoma									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Miscellaneous and site unspecified neoplasms malignant and unspecified									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Squamous cell carcinoma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Nasal cavity cancer									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Keratinising squamous cell carcinoma of nasopharynx									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Skeletal neoplasms benign									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Osteochondroma									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Breast neoplasms malignant and unspecified (incl nipple)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Invasive ductal breast carcinoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Endocrine neoplasms benign									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Pituitary tumour benign									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Endocrine neoplasms malignant and unspecified									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Neuroendocrine tumour									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal neoplasms malignant and unspecified									
Diabetes treatment group 1	3 (1.2)	3	0.9	0			2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	0			0		
Adenocarcinoma gastric									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Adenocarcinoma of colon									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Gastric cancer									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Gastric cancer stage IV									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Gastrointestinal stromal tumour									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Gastrointestinal submucosal tumour									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Oral neoplasm									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Hepatobiliary neoplasms malignant and unspecified									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(0.6)	1 0.4
Hepatocellular carcinoma									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4
Metastases												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Metastases to liver												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Reproductive neoplasms female benign												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Uterine leiomyoma												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Reproductive neoplasms female malignant and unspecified												
Diabetes treatment group 1	1	(0.4)	1	0.3	0				0			
Diabetes treatment group 2	0				0				0			
Uterine cancer												
Diabetes treatment group 1	1	(0.4)	1	0.3	0				0			
Diabetes treatment group 2	0				0				0			
Reproductive neoplasms male malignant and unspecified												

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Prostate cancer									
Diabetes treatment group 1	0			0			2 (0.9)	2	0.7
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Skin neoplasms malignant and unspecified									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Basal cell carcinoma									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hepatobiliary disorders									
Diabetes treatment group 1	5 (2.1)	5	1.6	9 (3.9)	12	3.9	7 (3.0)	9	3.0
Diabetes treatment group 2	5 (3.1)	6	2.8	1 (0.6)	1	0.4	2 (1.2)	5	2.2
Hepatic and hepatobiliary disorders									
Diabetes treatment group 1	3 (1.2)	3	0.9	8 (3.5)	9	2.9	7 (3.0)	7	2.3
Diabetes treatment group 2	3 (1.9)	3	1.4	0			2 (1.2)	3	1.3
Hepatic steatosis									
Diabetes treatment group 1	2 (0.8)	2	0.6	4 (1.7)	4	1.3	5 (2.2)	5	1.6
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Hepatic cyst									

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (0.4)	1	0.3	1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Hepatic lesion									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Non-alcoholic steatohepatitis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Nonalcoholic fatty liver disease									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Portal vein thrombosis									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Drug-induced liver injury									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Hepatic cirrhosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Hepatomegaly									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Liver disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	0			0		
Portal hypertension									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Gallbladder disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	3	1.0	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	3	1.4	1 (0.6)	1	0.4	1 (0.6)	2	0.9
Gallbladder polyp									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Cholecystitis chronic									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Cholelithiasis									
Diabetes treatment group 1	1 (0.4)	1	0.3	1 (0.4)	1	0.3	2 (0.9)	2	0.7
Diabetes treatment group 2	2 (1.3)	2	0.9	0			1 (0.6)	1	0.4
Cholecystitis acute									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Immune system disorders									

Adverse events with onset prior to randomisation are not included.
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Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	5 (2.1)	5	1.6	4 (1.7)	4	1.3	2 (0.9)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	4 (2.3)	4	1.8
Allergic conditions									
Diabetes treatment group 1	4 (1.6)	4	1.3	4 (1.7)	4	1.3	2 (0.9)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	4 (2.3)	4	1.8
Seasonal allergy									
Diabetes treatment group 1	2 (0.8)	2	0.6	4 (1.7)	4	1.3	2 (0.9)	3	1.0
Diabetes treatment group 2	0			0			2 (1.2)	2	0.9
Allergy to arthropod sting									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	1 (0.6)	1	0.4
Hypersensitivity									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	1 (0.6)	1	0.4	0		
Allergy to chemicals									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Drug hypersensitivity									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Multiple allergies									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Immune disorders NEC									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Immunisation reaction									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Endocrine disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Thyroid gland disorders									
Diabetes treatment group 1	2 (0.8)	2	0.6	2 (0.9)	2	0.7	3 (1.3)	3	1.0
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	1 (0.6)	1	0.4
Hypothyroidism									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (0.6)	1	0.5	2 (1.2)	2	0.9	0		
Primary hyperthyroidism									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Thyroid cyst									
Diabetes treatment group 1	0			1 (0.4)	1	0.3	0		
Diabetes treatment group 2	0			0			0		
Autoimmune thyroiditis									

Adverse events with onset prior to randomisation are not included.
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MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Goitre									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			0		
Silent thyroiditis									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			0		
Diabetes treatment group 2	0			0			0		
Thyroid mass									
Diabetes treatment group 1	0			0			1 (0.4)	1	0.3
Diabetes treatment group 2	0			0			1 (0.6)	1	0.4
Surgical and medical procedures									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			2 (0.9)	3	1.0
Diabetes treatment group 2	2 (1.3)	2	0.9	1 (0.6)	1	0.4	3 (1.7)	3	1.3
Endocrine gland therapeutic procedures									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Thyroidectomy									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (0.6)	1	0.4	0		
Bone and joint therapeutic procedures									
Diabetes treatment group 1	1 (0.4)	1	0.3	0			1 (0.4)	1	0.3

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Bone graft									
Diabetes treatment group 1	1	(0.4)	1 0.3	0			0		
Diabetes treatment group 2	0			0			0		
Joint injection									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Cardiac therapeutic procedures									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Cardiac pacemaker replacement									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Eye therapeutic procedures									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Cataract operation									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Head and neck therapeutic procedures									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Tooth extraction									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(0.6)	1	0.5	0				0			
Male genital tract therapeutic procedures												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4
Sperm aspiration												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4
Therapeutic procedures and supportive care NEC												
Diabetes treatment group 1	0				0				1	(0.4)	1	0.3
Diabetes treatment group 2	0				0				2	(1.2)	2	0.9
Cyst removal												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4
Nerve block												
Diabetes treatment group 1	0				0				1	(0.4)	1	0.3
Diabetes treatment group 2	0				0				0			
Stent placement												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(0.6)	1	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Congenital, familial and genetic disorders									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Reproductive tract and breast disorders congenital									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Phimosis									
Diabetes treatment group 1	0			0			2	(0.9)	2 0.7
Diabetes treatment group 2	0			0			0		
Respiratory disorders congenital									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Laryngeal web									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(0.6)	1 0.5	0			0		
Pregnancy, puerperium and perinatal conditions									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Abortions and stillbirth									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Abortion spontaneous									
Diabetes treatment group 1	0			0			1	(0.4)	1 0.3
Diabetes treatment group 2	0			0			0		
Social circumstances									
Diabetes treatment group 1	2	(0.8)	2 0.6	0			0		
Diabetes treatment group 2	0			0			0		
Economic and housing issues									
Diabetes treatment group 1	2	(0.8)	2 0.6	0			0		
Diabetes treatment group 2	0			0			0		
Stress at work									
Diabetes treatment group 1	2	(0.8)	2 0.6	0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

49 Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
Diabetes treatment group 1	9	12.8			27	37.2			12	17.1		
Diabetes treatment group 2	16	22.7			22	31.1			13	18.5		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
Diabetes treatment group 1	7	(77.8)	28	218.3	18	(66.7)	129	346.9	11	(91.7)	27	157.8
Diabetes treatment group 2	15	(93.8)	60	264.2	20	(90.9)	119	382.9	9	(69.2)	25	135.0
Serious												
Yes												
Diabetes treatment group 1	0				2	(7.4)	2	5.4	2	(16.7)	2	11.7
Diabetes treatment group 2	0				0				0			
No												
Diabetes treatment group 1	7	(77.8)	28	218.3	18	(66.7)	127	341.5	11	(91.7)	25	146.1
Diabetes treatment group 2	15	(93.8)	60	264.2	20	(90.9)	119	382.9	9	(69.2)	25	135.0
Severity												
Moderate												
Diabetes treatment group 1	0				4	(14.8)	4	10.8	4	(33.3)	4	23.4
Diabetes treatment group 2	4	(25.0)	5	22.0	3	(13.6)	4	12.9	0			
Mild												
Diabetes treatment group 1	7	(77.8)	28	218.3	18	(66.7)	125	336.1	11	(91.7)	23	134.4
Diabetes treatment group 2	14	(87.5)	55	242.2	20	(90.9)	115	370.1	9	(69.2)	25	135.0

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Relationship to trial product									
Probable									
Diabetes treatment group 1	3 (33.3)	3	23.4	11 (40.7)	41	110.2	1 (8.3)	1	5.8
Diabetes treatment group 2	2 (12.5)	3	13.2	6 (27.3)	19	61.1	1 (7.7)	2	10.8
Possible									
Diabetes treatment group 1	3 (33.3)	4	31.2	11 (40.7)	30	80.7	2 (16.7)	6	35.1
Diabetes treatment group 2	10 (62.5)	16	70.5	14 (63.6)	22	70.8	0		
Unlikely									
Diabetes treatment group 1	7 (77.8)	21	163.7	17 (63.0)	58	156.0	9 (75.0)	20	116.9
Diabetes treatment group 2	14 (87.5)	41	180.6	17 (77.3)	78	251.0	9 (69.2)	23	124.2
Outcome									
Recovered									
Diabetes treatment group 1	7 (77.8)	22	171.5	18 (66.7)	113	303.9	10 (83.3)	20	116.9
Diabetes treatment group 2	13 (81.3)	43	189.4	19 (86.4)	108	347.6	8 (61.5)	18	97.2
Recovering									
Diabetes treatment group 1	1 (11.1)	2	15.6	3 (11.1)	4	10.8	1 (8.3)	1	5.8
Diabetes treatment group 2	3 (18.8)	5	22.0	4 (18.2)	5	16.1	1 (7.7)	1	5.4
Not Recovered									
Diabetes treatment group 1	4 (44.4)	4	31.2	8 (29.6)	12	32.3	4 (33.3)	6	35.1
Diabetes treatment group 2	9 (56.3)	12	52.8	4 (18.2)	6	19.3	3 (23.1)	6	32.4

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by background diabetes treatment - overview - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Leading to												
Permanent treatment discontinuation												
Diabetes treatment group 1	0				1	(3.7)	3	8.1	0			
Diabetes treatment group 2	0				0				0			
Temporary interruption of trial product												
Diabetes treatment group 1	0				5	(18.5)	5	13.4	1	(8.3)	1	5.8
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Dose reduction of trial product												
Diabetes treatment group 1	0				3	(11.1)	5	13.4	0			
Diabetes treatment group 2	0				2	(9.1)	2	6.4	0			

Adverse events with onset prior to randomisation are not included.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

50 Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
Diabetes treatment group 1	9		12.8		27		37.2		12		17.1	
Diabetes treatment group 2	16		22.7		22		31.1		13		18.5	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
Diabetes treatment group 1	7	(77.8)	28	218.3	18	(66.7)	129	346.9	11	(91.7)	27	157.8
Diabetes treatment group 2	15	(93.8)	60	264.2	20	(90.9)	119	382.9	9	(69.2)	25	135.0
Gastrointestinal disorders												
Diabetes treatment group 1	5	(55.6)	11	85.8	16	(59.3)	49	131.8	2	(16.7)	2	11.7
Diabetes treatment group 2	10	(62.5)	18	79.3	16	(72.7)	43	138.4	5	(38.5)	6	32.4
Gastrointestinal motility and defaecation conditions												
Diabetes treatment group 1	3	(33.3)	6	46.8	13	(48.1)	20	53.8	1	(8.3)	1	5.8
Diabetes treatment group 2	6	(37.5)	7	30.8	10	(45.5)	18	57.9	1	(7.7)	1	5.4
Constipation												
Diabetes treatment group 1	2	(22.2)	2	15.6	9	(33.3)	10	26.9	0			
Diabetes treatment group 2	1	(6.3)	2	8.8	8	(36.4)	8	25.7	0			
Diarrhoea												
Diabetes treatment group 1	2	(22.2)	4	31.2	6	(22.2)	10	26.9	1	(8.3)	1	5.8
Diabetes treatment group 2	3	(18.8)	3	13.2	3	(13.6)	9	29.0	1	(7.7)	1	5.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrooesophageal reflux disease									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	2 (12.5)	2	8.8	1 (4.5)	1	3.2	0		
Gastrointestinal motility disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Irritable bowel syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal signs and symptoms									
Diabetes treatment group 1	2 (22.2)	3	23.4	10 (37.0)	23	61.8	0		
Diabetes treatment group 2	5 (31.3)	8	35.2	9 (40.9)	18	57.9	1 (7.7)	1	5.4
Nausea									
Diabetes treatment group 1	2 (22.2)	2	15.6	5 (18.5)	10	26.9	0		
Diabetes treatment group 2	3 (18.8)	3	13.2	6 (27.3)	8	25.7	0		
Vomiting									
Diabetes treatment group 1	0			2 (7.4)	3	8.1	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	2 (9.1)	5	16.1	1 (7.7)	1	5.4
Abdominal discomfort									
Diabetes treatment group 1	1 (11.1)	1	7.8	2 (7.4)	3	8.1	0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Abdominal pain									
Diabetes treatment group 1	0			2 (7.4)	2	5.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				1	(4.5)	2	6.4	0			
Abdominal distension												
Diabetes treatment group 1	0				1	(3.7)	2	5.4	0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Abdominal pain upper												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	1	(6.3)	2	8.8	1	(4.5)	1	3.2	0			
Abdominal tenderness												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Dyspepsia												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Abdominal pain lower												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Epigastric discomfort												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Eructation												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Faeces hard												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Faeces soft									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Flatulence									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Dental and gingival conditions									
Diabetes treatment group 1	0			2	(7.4)	2 5.4	0		
Diabetes treatment group 2	1	(6.3)	1 4.4	2	(9.1)	2 6.4	2	(15.4)	2 10.8
Dental caries									
Diabetes treatment group 1	0			2	(7.4)	2 5.4	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	2	(15.4)	2 10.8
Toothache									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	1	(4.5)	1 3.2	0		
Dental cyst									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Tooth impacted									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal inflammatory conditions									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			3 (13.6)	3	9.7	1 (7.7)	1	5.4
Colitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Enterocolitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Gastritis									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Chronic gastritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Colitis ischaemic									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Enteritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal conditions NEC									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	2 (12.5)	2	8.8	1 (4.5)	2	6.4	0		
Gastrointestinal disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	2	6.4	0		
Gastric disorder									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Barrett's oesophagus									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Food poisoning									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Benign neoplasms gastrointestinal									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Large intestine polyp									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Gastric polyps									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Rectal polyp												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Diverticular disorders												
Diabetes treatment group 1	1	(11.1)	1	7.8	1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Diverticulum intestinal												
Diabetes treatment group 1	1	(11.1)	1	7.8	1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Oral soft tissue conditions												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Angular cheilitis												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Stomatitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Anal and rectal conditions NEC												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Anal fissure												
Diabetes treatment group 1	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Gastrointestinal haemorrhages NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Anal haemorrhage									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Mallory-Weiss syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal stenosis and obstruction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Intestinal obstruction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal ulceration and perforation									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Erosive duodenitis									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			0			0		
Gastritis erosive									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal vascular conditions									
Diabetes treatment group 1	1 (11.1)	1	7.8	0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Haemorrhoids									
Diabetes treatment group 1	1 (11.1)	1	7.8	0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Salivary gland conditions									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Parotid gland enlargement									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Infections and infestations									
Diabetes treatment group 1	5 (55.6)	7	54.6	11 (40.7)	22	59.2	5 (41.7)	5	29.2
Diabetes treatment group 2	11 (68.8)	13	57.2	9 (40.9)	27	86.9	3 (23.1)	6	32.4
Infections - pathogen unspecified									
Diabetes treatment group 1	5 (55.6)	7	54.6	10 (37.0)	21	56.5	4 (33.3)	4	23.4
Diabetes treatment group 2	10 (62.5)	12	52.8	7 (31.8)	20	64.4	3 (23.1)	5	27.0

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Nasopharyngitis									
Diabetes treatment group 1	3 (33.3)	5	39.0	6 (22.2)	10	26.9	2 (16.7)	2	11.7
Diabetes treatment group 2	7 (43.8)	7	30.8	7 (31.8)	9	29.0	2 (15.4)	3	16.2
Bronchitis									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	2 (9.1)	4	12.9	0		
Gastroenteritis									
Diabetes treatment group 1	0			2 (7.4)	4	10.8	0		
Diabetes treatment group 2	2 (12.5)	2	8.8	1 (4.5)	1	3.2	0		
Pharyngitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			2 (9.1)	3	9.7	0		
Cystitis									
Diabetes treatment group 1	0			2 (7.4)	2	5.4	0		
Diabetes treatment group 2	0			0			0		
Acute sinusitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Folliculitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	0		
Hordeolum									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Urinary tract infection												
Diabetes treatment group 1	1	(11.1)	1	7.8	1	(3.7)	3	8.1	0			
Diabetes treatment group 2	0				0				0			
Conjunctivitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				1	(7.7)	1	5.4
Diverticulitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Enteritis infectious												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Gingivitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Pelvic inflammatory disease												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Periodontitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Pyelonephritis												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Pyelonephritis acute												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Pyoderma												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Rhinitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Sinusitis												
Diabetes treatment group 1	0				0				2	(16.7)	2	11.7
Diabetes treatment group 2	0				0				0			
Tonsillitis												
Diabetes treatment group 1	1	(11.1)	1	7.8	0				0			
Diabetes treatment group 2	0				0				1	(7.7)	1	5.4
Upper respiratory tract infection												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Urethritis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vaginal infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Viral infectious disorders									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	1 (8.3)	1	5.8
Diabetes treatment group 2	1 (6.3)	1	4.4	3 (13.6)	3	9.7	0		
Influenza									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	1 (8.3)	1	5.8
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Gastroenteritis viral									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Herpes zoster									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	1	3.2	0		
Herpes simplex									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Infectious mononucleosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Bacterial infectious disorders									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 2	0			2 (9.1)	3	9.7	1 (7.7)	1	5.4
Alpha haemolytic streptococcal infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Erysipelas									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	0		
Cellulitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Furuncle									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Helicobacter infection									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Fungal infectious disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Tinea pedis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Vulvovaginal candidiasis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Musculoskeletal and connective tissue disorders									
Diabetes treatment group 1	3	(33.3)	4 31.2	3	(11.1)	4 10.8	3	(25.0)	4 23.4
Diabetes treatment group 2	7	(43.8)	8 35.2	8	(36.4)	12 38.6	5	(38.5)	7 37.8
Joint disorders									
Diabetes treatment group 1	3	(33.3)	4 31.2	1	(3.7)	1 2.7	1	(8.3)	1 5.8
Diabetes treatment group 2	5	(31.3)	5 22.0	4	(18.2)	4 12.9	3	(23.1)	4 21.6
Arthralgia									
Diabetes treatment group 1	1	(11.1)	1 7.8	0			0		
Diabetes treatment group 2	4	(25.0)	4 17.6	2	(9.1)	2 6.4	2	(15.4)	2 10.8
Periarthritis									
Diabetes treatment group 1	1	(11.1)	1 7.8	1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Rotator cuff syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Arthritis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Articular calcification									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(7.7)	2 10.8
Osteoarthritis									
Diabetes treatment group 1	2	(22.2)	2 15.6	0			0		
Diabetes treatment group 2	0			0			0		
Spinal osteoarthritis									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Musculoskeletal and connective tissue disorders NEC									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	1	(8.3)	2 11.7
Diabetes treatment group 2	2	(12.5)	2 8.8	4	(18.2)	5 16.1	3	(23.1)	3 16.2
Back pain									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	1	(8.3)	2 11.7
Diabetes treatment group 2	1	(6.3)	1 4.4	4	(18.2)	5 16.1	1	(7.7)	1 5.4
Musculoskeletal discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Musculoskeletal pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(7.7)	1 5.4
Musculoskeletal stiffness									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Neck pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(7.7)	1 5.4
Pain in extremity									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Muscle disorders									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Myalgia									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Fibromyalgia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Muscle spasms									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Rhabdomyolysis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Tendon, ligament and cartilage disorders									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	0		
Trigger finger									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	0		
Tendonitis									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Intervertebral disc protrusion									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Spinal stenosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Synovial and bursal disorders									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Bursitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Synovitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Eye disorders									
Diabetes treatment group 1	0			5	(18.5)	6 16.1	1	(8.3)	2 11.7
Diabetes treatment group 2	3	(18.8)	4 17.6	6	(27.3)	6 19.3	2	(15.4)	2 10.8
Retina, choroid and vitreous haemorrhages and vascular disorders									
Diabetes treatment group 1	0			2	(7.4)	2 5.4	1	(8.3)	1 5.8
Diabetes treatment group 2	1	(6.3)	2 8.8	3	(13.6)	3 9.7	1	(7.7)	1 5.4
Diabetic retinopathy									
Diabetes treatment group 1	0			2	(7.4)	2 5.4	1	(8.3)	1 5.8
Diabetes treatment group 2	1	(6.3)	2 8.8	1	(4.5)	1 3.2	1	(7.7)	1 5.4
Retinal exudates									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Retinal haemorrhage									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Retinopathy												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Ocular infections, irritations and inflammations												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Conjunctivitis allergic												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Ocular hyperaemia												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Vision disorders												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Visual acuity reduced												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Amblyopia												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Optic nerve disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Presbyopia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Ocular structural change, deposit and degeneration NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	1	(4.5)	1 3.2	0		
Retinal tear									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Macular fibrosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Rhegmatogenous retinal detachment									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Glaucoma and ocular hypertension									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			1	(7.7)	1 5.4
Glaucoma									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Open angle glaucoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Ocular haemorrhages and vascular disorders NEC									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Optic disc haemorrhage									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Conjunctival haemorrhage									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Anterior eye structural change, deposit and degeneration									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			0			0		
Cataract									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			0			0		
Eye disorders NEC									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Dry eye									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Lacrimal disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Lacrimation increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Nervous system disorders									
Diabetes treatment group 1	0			6	(22.2)	9 24.2	0		
Diabetes treatment group 2	0			5	(22.7)	6 19.3	1	(7.7)	1 5.4
Neurological disorders NEC									
Diabetes treatment group 1	0			3	(11.1)	4 10.8	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Dizziness									
Diabetes treatment group 1	0			2	(7.4)	2 5.4	0		
Diabetes treatment group 2	0			0			0		
Somnolence									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Hypoaesthesia												
Diabetes treatment group 1	0				1	(3.7)	2	5.4	0			
Diabetes treatment group 2	0				0				0			
Dizziness postural												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Dysaesthesia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Dysgeusia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Intercostal neuralgia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Neuralgia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Neurological symptom												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Paraesthesia												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Sensory loss									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Taste disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Headaches									
Diabetes treatment group 1	0			1 (3.7)	2	5.4	0		
Diabetes treatment group 2	0			2 (9.1)	3	9.7	1 (7.7)	1	5.4
Headache									
Diabetes treatment group 1	0			1 (3.7)	2	5.4	0		
Diabetes treatment group 2	0			2 (9.1)	3	9.7	1 (7.7)	1	5.4
Spinal cord and nerve root disorders									
Diabetes treatment group 1	0			2 (7.4)	2	5.4	0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Sciatica									
Diabetes treatment group 1	0			2 (7.4)	2	5.4	0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Cranial nerve disorders (excl neoplasms)									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Parosmia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Neuromuscular disorders									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Autonomic nervous system imbalance									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Central nervous system vascular disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Lacunar infarction									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Peripheral neuropathies									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Carpal tunnel syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
General disorders and administration site conditions									
Diabetes treatment group 1	0			5 (18.5)	18	48.4	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	2 (9.1)	3	9.7	1 (7.7)	1	5.4
General system disorders NEC									
Diabetes treatment group 1	0			3 (11.1)	5	13.4	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	2 (9.1)	3	9.7	1 (7.7)	1	5.4
Malaise									
Diabetes treatment group 1	0			2 (7.4)	3	8.1	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	2	6.4	0		
Non-cardiac chest pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Feeling abnormal									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Oedema peripheral									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Fatigue									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hangover									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hunger									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1	(7.7)	1 5.4
Influenza like illness									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Thirst									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Administration site reactions									
Diabetes treatment group 1	0			2	(7.4)	13 35.0	0		
Diabetes treatment group 2	0			0			0		
Injection site dermatitis									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Injection site erythema									
Diabetes treatment group 1	0			1	(3.7)	12 32.3	0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Injection site discomfort									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Body temperature conditions									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Pyrexia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Injury, poisoning and procedural complications									
Diabetes treatment group 1	1	(11.1)	1 7.8	5	(18.5)	5 13.4	1	(8.3)	1 5.8
Diabetes treatment group 2	1	(6.3)	2 8.8	2	(9.1)	2 6.4	0		
Injuries NEC									
Diabetes treatment group 1	0			4	(14.8)	4 10.8	0		
Diabetes treatment group 2	1	(6.3)	2 8.8	2	(9.1)	2 6.4	0		
Subcutaneous haematoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Tooth fracture									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Arthropod bite									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Contusion									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Limb injury									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Tendon rupture									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Arthropod sting									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Epicondylitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Ligament sprain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	2 8.8	0			0		
Limb crushing injury									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Muscle contusion									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Muscle strain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Post-traumatic neck syndrome									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Road traffic accident									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Skin laceration									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Subdural haematoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Bone and joint injuries									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	1 (8.3)	1	5.8
Diabetes treatment group 2	0			0			0		
Ankle fracture									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Fracture												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Joint injury												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Meniscus injury												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Radius fracture												
Diabetes treatment group 1	0				0				1	(8.3)	1	5.8
Diabetes treatment group 2	0				0				0			
Rib fracture												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Injuries by physical agents												
Diabetes treatment group 1	1	(11.1)	1	7.8	0				0			
Diabetes treatment group 2	0				0				0			
Heat illness												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Heat stroke												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (11.1)	1	7.8	0			0		
Diabetes treatment group 2	0			0			0		
Thermal burn									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Medication errors and other product use errors and issues									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Accidental overdose									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Product administration error									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Skin and subcutaneous tissue disorders									
Diabetes treatment group 1	2 (22.2)	2	15.6	3 (11.1)	4	10.8	1 (8.3)	1	5.8
Diabetes treatment group 2	3 (18.8)	5	22.0	3 (13.6)	3	9.7	0		
Epidermal and dermal conditions									
Diabetes treatment group 1	1 (11.1)	1	7.8	3 (11.1)	4	10.8	1 (8.3)	1	5.8
Diabetes treatment group 2	3 (18.8)	4	17.6	2 (9.1)	2	6.4	0		
Eczema									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				0				1	(8.3)	1	5.8
Diabetes treatment group 2	3	(18.8)	3	13.2	1	(4.5)	1	3.2	0			
Pruritus												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Dermatitis												
Diabetes treatment group 1	0				1	(3.7)	2	5.4	0			
Diabetes treatment group 2	0				0				0			
Dermatitis contact												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Erythema												
Diabetes treatment group 1	1	(11.1)	1	7.8	1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Dermatitis atopic												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Drug eruption												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Dry skin												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Dyshidrotic eczema									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Eczema asteatotic									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Pain of skin									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Rash									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Rash pruritic									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Seborrhoeic dermatitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Stasis dermatitis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Xanthelasma									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Skin appendage conditions												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Miliaria												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Acne												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Alopecia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Alopecia areata												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Ingrowing nail												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Angioedema and urticaria												
Diabetes treatment group 1	1	(11.1)	1	7.8	0				0			
Diabetes treatment group 2	0				0				0			
Urticaria												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	1 (11.1)	1	7.8	0			0		
Diabetes treatment group 2	0			0			0		
Cornification and dystrophic skin disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hyperkeratosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Xeroderma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Metabolism and nutrition disorders									
Diabetes treatment group 1	1 (11.1)	1	7.8	4 (14.8)	4	10.8	3 (25.0)	5	29.2
Diabetes treatment group 2	1 (6.3)	1	4.4	2 (9.1)	3	9.7	1 (7.7)	1	5.4
Appetite and general nutritional disorders									
Diabetes treatment group 1	1 (11.1)	1	7.8	2 (7.4)	2	5.4	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	1	3.2	0		
Decreased appetite									
Diabetes treatment group 1	1 (11.1)	1	7.8	2 (7.4)	2	5.4	0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	1	3.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Glucose metabolism disorders (incl diabetes mellitus)									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	1 (7.7)	1	5.4
Type 2 diabetes mellitus									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	2	6.4	0		
Diabetes mellitus									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Glucose tolerance impaired									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Electrolyte and fluid balance conditions									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Dehydration									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Lipid metabolism disorders									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dyslipidaemia									
Diabetes treatment group 1	0			0			1 (8.3)	1	5.8
Diabetes treatment group 2	0			0			0		
Metabolism disorders NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hypercreatininaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Purine and pyrimidine metabolism disorders									
Diabetes treatment group 1	0			0			3 (25.0)	4	23.4
Diabetes treatment group 2	0			0			0		
Gout									
Diabetes treatment group 1	0			0			1 (8.3)	2	11.7
Diabetes treatment group 2	0			0			0		
Hyperuricaemia									
Diabetes treatment group 1	0			0			2 (16.7)	2	11.7
Diabetes treatment group 2	0			0			0		
Respiratory, thoracic and mediastinal disorders									
Diabetes treatment group 1	1 (11.1)	1	7.8	1 (3.7)	1	2.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	1	(6.3)	2	8.8	4	(18.2)	5	16.1	0			
Upper respiratory tract disorders (excl infections)												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				2	(9.1)	2	6.4	0			
Rhinitis allergic												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				2	(9.1)	2	6.4	0			
Epistaxis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Vasomotor rhinitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Respiratory tract signs and symptoms												
Diabetes treatment group 1	1	(11.1)	1	7.8	1	(3.7)	1	2.7	0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Upper respiratory tract inflammation												
Diabetes treatment group 1	1	(11.1)	1	7.8	0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Hiccups												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Oropharyngeal pain									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Rhinorrhoea									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Bronchial disorders (excl neoplasms)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (6.3)	1	4.4	1 (4.5)	1	3.2	0		
Asthma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Cough variant asthma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Respiratory disorders NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Dyspnoea									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Cough									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Investigations												
Diabetes treatment group 1	0				2	(7.4)	3	8.1	2	(16.7)	2	11.7
Diabetes treatment group 2	2	(12.5)	2	8.8	3	(13.6)	4	12.9	0			
Endocrine investigations (incl sex hormones)												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Blood thyroid stimulating hormone decreased												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Enzyme investigations NEC												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Blood creatine phosphokinase increased												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Gastrointestinal investigations												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	2	6.4	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Amylase increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Lipase increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	1	(4.5)	1 3.2	0		
Occult blood positive									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Cardiac and vascular investigations (excl enzyme tests)									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Blood pressure decreased									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Electrocardiogram QRS complex prolonged									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Electrocardiogram QT prolonged									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Haematology investigations (incl blood groups)												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Haemoglobin decreased												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Lymphocyte count decreased												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
White blood cell count increased												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Physical examination and organ system status topics												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Weight decreased												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Hepatobiliary investigations												
Diabetes treatment group 1	0				0				1	(8.3)	1	5.8
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Alanine aminotransferase increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Aspartate aminotransferase increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Blood bilirubin increased									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Liver function test increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Lipid analyses									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Blood triglycerides increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Metabolic, nutritional and blood gas investigations									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Blood uric acid increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Glycosylated haemoglobin increased									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Protein and chemistry analyses NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
C-reactive protein increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Water, electrolyte and mineral investigations									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Blood potassium increased									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Congenital, familial and genetic disorders									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Skin and subcutaneous tissue disorders congenital									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Birth mark									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Gastrointestinal tract disorders congenital									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Diverticulitis Meckel's									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Psychiatric disorders									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	1 (7.7)	1	5.4
Sleep disorders and disturbances									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		
Insomnia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1 (4.5)	1	3.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Depressed mood disorders and disturbances									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Depression									
Diabetes treatment group 1	0			1 (3.7)	1	2.7	0		
Diabetes treatment group 2	0			0			0		
Adjustment disorders (incl subtypes)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Adjustment disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Mood disorders and disturbances NEC									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Emotional disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Listless									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			1 (7.7)	1	5.4
Vascular disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Arteriosclerosis, stenosis, vascular insufficiency and necrosis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Arteriosclerosis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Decreased and nonspecific blood pressure disorders and shock												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Hypotension												
Diabetes treatment group 1	0				1	(3.7)	1	2.7	0			
Diabetes treatment group 2	0				0				0			
Orthostatic hypotension												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Embolism and thrombosis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Venous thrombosis limb												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Vascular hypertensive disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Hypertension												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Endocrine disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Thyroid gland disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Hyperthyroidism												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				1	(4.5)	1	3.2	0			
Reproductive system and breast disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	1	(4.5)	1	3.2	0			
Menstrual cycle and uterine bleeding disorders												

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Dysmenorrhoea									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			1	(4.5)	1 3.2	0		
Menstrual disorder									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Menstruation irregular									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Breast disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Breast calcifications									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Male reproductive tract infections and inflammations									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Prostatitis									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Menopause related conditions												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Menopausal symptoms												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Prostatic disorders (excl infections and inflammations)												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Benign prostatic hyperplasia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Uterine, pelvic and broad ligament disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Endometrial hyperplasia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Endometriosis												
Diabetes treatment group 1	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Uterine haemorrhage									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Cardiac disorders									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Cardiac arrhythmias									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Tachycardia									
Diabetes treatment group 1	0			1	(3.7)	1 2.7	0		
Diabetes treatment group 2	0			0			0		
Arrhythmia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Atrial fibrillation									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Ventricular extrasystoles									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Cardiac disorders, signs and symptoms NEC												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Palpitations												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Coronary artery disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Acute myocardial infarction												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Blood and lymphatic system disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Anaemias nonhaemolytic and marrow depression												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Anaemia												
Diabetes treatment group 1	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Iron deficiency anaemia												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Spleen, lymphatic and reticuloendothelial system disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Lymphadenitis												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Ear and labyrinth disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	1	(6.3)	1	4.4	0				0			
Hearing disorders												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Deafness												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Deafness neurosensory												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Inner ear and VIIIth cranial nerve disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Tinnitus									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Vertigo									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Hepatobiliary disorders									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Gallbladder disorders									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Cholelithiasis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gallbladder polyp									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hyperplastic cholecystopathy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hepatic and hepatobiliary disorders									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Alcoholic liver disease									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Hepatic cyst									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hepatic function abnormal									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hepatic steatosis									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Immune system disorders									
Diabetes treatment group 1	1	(11.1)	1 7.8	0			0		
Diabetes treatment group 2	0			0			0		
Allergic conditions									
Diabetes treatment group 1	1	(11.1)	1 7.8	0			0		
Diabetes treatment group 2	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Food allergy												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Seasonal allergy												
Diabetes treatment group 1	1	(11.1)	1	7.8	0				0			
Diabetes treatment group 2	0				0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Gastrointestinal neoplasms benign												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Intraductal papillary mucinous neoplasm												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Hepatobiliary neoplasms malignant and unspecified												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			
Bile duct adenocarcinoma												
Diabetes treatment group 1	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	0			0			0		
Renal and urinary tract neoplasms malignant and unspecified									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Clear cell renal cell carcinoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Reproductive neoplasms female benign									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Uterine leiomyoma									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Lung neoplasm malignant									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Renal and urinary disorders									
Diabetes treatment group 1	0			0			2	(16.7)	3 17.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Diabetes treatment group 2	1	(6.3)	1 4.4	0			0		
Nephropathies									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Diabetic nephropathy									
Diabetes treatment group 1	0			0			1	(8.3)	1 5.8
Diabetes treatment group 2	0			0			0		
Nephropathy toxic									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Renal disorders (excl nephropathies)									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Azotaemia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Renal cyst									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Urinary tract signs and symptoms									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Hyperuricosuria									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Nocturia									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Proteinuria									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Urolithiases									
Diabetes treatment group 1	0			0			1 (8.3)	2	11.7
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Calculus urinary									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Ureterolithiasis									
Diabetes treatment group 1	0			0			1 (8.3)	2	11.7
Diabetes treatment group 2	1 (6.3)	1	4.4	0			0		
Surgical and medical procedures									
Diabetes treatment group 1	0			0			0		
Diabetes treatment group 2	0			0			0		
Gastrointestinal therapeutic procedures									
Diabetes treatment group 1	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by background diabetes treatment, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6 subjects with type 2 diabetes

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Diabetes treatment group 2	0				0				0			
Large intestinal polypectomy												
Diabetes treatment group 1	0				0				0			
Diabetes treatment group 2	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Diabetes treatment group 1 includes subjects on diet and physical activity only or treatment with SGLT2i. Diabetes treatment group 2 includes subjects on single compound OAD treatment (SU or glitazone) or combination treatment with up to three OADs (metformin, SU, SGLT2i or glitazone).
SGLT2i: Sodiumglucose co-transporter 2 inhibitors, OAD: Oral antidiabetic drug, SU: Sulphonylurea
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.,
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

51 Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
>= 20% Weight loss	388	549.1			10	14.2		
< 20% Weight loss	824	1092.6			567	761.4		
Missing	94	64.5			78	54.0		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Events								
>= 20% Weight loss	350	(90.2)	3129	569.9	10	(100)	47	331.5
< 20% Weight loss	743	(90.2)	6021	551.1	496	(87.5)	3027	397.5
Missing	78	(83.0)	508	788.0	60	(76.9)	228	422.6
Serious								
Yes								
>= 20% Weight loss	37	(9.5)	53	9.7	0			
< 20% Weight loss	85	(10.3)	104	9.5	36	(6.3)	47	6.2
Missing	6	(6.4)	7	10.9	6	(7.7)	6	11.1
No								
>= 20% Weight loss	350	(90.2)	3076	560.2	10	(100)	47	331.5
< 20% Weight loss	741	(89.9)	5917	541.6	493	(86.9)	2980	391.4
Missing	78	(83.0)	501	777.1	57	(73.1)	222	411.5
Severity								
Severe								
>= 20% Weight loss	46	(11.9)	77	14.0	1	(10.0)	1	7.1
< 20% Weight loss	89	(10.8)	142	13.0	36	(6.3)	59	7.7
Missing	8	(8.5)	23	35.7	7	(9.0)	8	14.8
Moderate								
>= 20% Weight loss	230	(59.3)	860	156.6	6	(60.0)	16	112.9

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Severity								
Moderate								
< 20% Weight loss	449	(54.5)	1602	146.6	276	(48.7)	777	102.0
Missing	44	(46.8)	150	232.7	29	(37.2)	70	129.7
Mild								
>= 20% Weight loss	326	(84.0)	2192	399.2	10	(100)	30	211.6
< 20% Weight loss	687	(83.4)	4277	391.5	446	(78.7)	2191	287.7
Missing	66	(70.2)	335	519.6	51	(65.4)	150	278.0
Relationship to trial product								
Missing								
>= 20% Weight loss	5	(1.3)	5	0.9	0			
< 20% Weight loss	19	(2.3)	25	2.3	5	(0.9)	6	0.8
Missing	0				2	(2.6)	2	3.7
Probable								
>= 20% Weight loss	176	(45.4)	675	122.9	1	(10.0)	1	7.1
< 20% Weight loss	355	(43.1)	1332	121.9	132	(23.3)	308	40.4
Missing	40	(42.6)	141	218.7	14	(17.9)	21	38.9
Possible								
>= 20% Weight loss	231	(59.5)	876	159.5	1	(10.0)	5	35.3
< 20% Weight loss	450	(54.6)	1664	152.3	198	(34.9)	490	64.4
Missing	45	(47.9)	160	248.2	24	(30.8)	60	111.2
Unlikely								
>= 20% Weight loss	320	(82.5)	1573	286.5	10	(100)	41	289.2
< 20% Weight loss	652	(79.1)	3000	274.6	473	(83.4)	2223	291.9
Missing	60	(63.8)	207	321.1	53	(67.9)	145	268.8
Outcome								
Fatal								
>= 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
< 20% Weight loss	0				0			
Missing	0				1	(1.3)	1	1.9
Recovered								
>= 20% Weight loss	347	(89.4)	2759	502.5	10	(100)	37	261.0
< 20% Weight loss	721	(87.5)	5245	480.1	481	(84.8)	2504	328.9
Missing	72	(76.6)	435	674.8	54	(69.2)	169	313.2
Recovering								
>= 20% Weight loss	19	(4.9)	34	6.2	1	(10.0)	2	14.1
< 20% Weight loss	38	(4.6)	51	4.7	24	(4.2)	35	4.6
Missing	2	(2.1)	6	9.3	0			
Recovered With Sequelae								
>= 20% Weight loss	3	(0.8)	8	1.5	0			
< 20% Weight loss	7	(0.8)	10	0.9	3	(0.5)	4	0.5
Missing	1	(1.1)	1	1.6	1	(1.3)	1	1.9
Not Recovered								
>= 20% Weight loss	148	(38.1)	328	59.7	4	(40.0)	8	56.4
< 20% Weight loss	333	(40.4)	715	65.4	235	(41.4)	484	63.6
Missing	32	(34.0)	63	97.7	26	(33.3)	56	103.8
Unknown								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	2	(2.1)	3	4.7	1	(1.3)	1	1.9
Leading to								
Permanent treatment discontinuation								
>= 20% Weight loss	9	(2.3)	12	2.2	0			
< 20% Weight loss	64	(7.8)	89	8.1	14	(2.5)	17	2.2
Missing	19	(20.2)	22	34.1	6	(7.7)	6	11.1

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Leading to								
Temporary interruption of trial product								
>= 20% Weight loss	23	(5.9)	42	7.6	0			
< 20% Weight loss	92	(11.2)	202	18.5	21	(3.7)	38	5.0
Missing	11	(11.7)	21	32.6	5	(6.4)	6	11.1
Dose reduction of trial product								
>= 20% Weight loss	45	(11.6)	74	13.5	0			
< 20% Weight loss	66	(8.0)	129	11.8	4	(0.7)	9	1.2
Missing	13	(13.8)	22	34.1	0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

52 Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE		
>= 20% Weight loss	388	549.1			10	14.2		
< 20% Weight loss	824	1092.6			567	761.4		
Missing	94	64.5			78	54.0		
Subjects with events	N	(%)	E	R	N	(%)	E	R
Adverse events								
>= 20% Weight loss	350	(90.2)	3129	569.9	10	(100)	47	331.5
< 20% Weight loss	743	(90.2)	6021	551.1	496	(87.5)	3027	397.5
Missing	78	(83.0)	508	788.0	60	(76.9)	228	422.6
Gastrointestinal disorders								
>= 20% Weight loss	297	(76.5)	1394	253.9	5	(50.0)	11	77.6
< 20% Weight loss	610	(74.0)	2654	242.9	276	(48.7)	665	87.3
Missing	62	(66.0)	261	404.9	33	(42.3)	63	116.8
Gastrointestinal signs and symptoms								
>= 20% Weight loss	263	(67.8)	916	166.8	2	(20.0)	2	14.1
< 20% Weight loss	506	(61.4)	1608	147.2	178	(31.4)	351	46.1
Missing	55	(58.5)	190	294.7	21	(26.9)	42	77.8
Nausea								
>= 20% Weight loss	199	(51.3)	387	70.5	1	(10.0)	1	7.1
< 20% Weight loss	333	(40.4)	592	54.2	98	(17.3)	126	16.5
Missing	45	(47.9)	89	138.1	15	(19.2)	19	35.2
Vomiting								
>= 20% Weight loss	110	(28.4)	220	40.1	0			
< 20% Weight loss	183	(22.2)	364	33.3	38	(6.7)	45	5.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	31 (33.0)	52	80.7	5 (6.4)	7	13.0
Abdominal pain upper						
>= 20% Weight loss	45 (11.6)	62	11.3	1 (10.0)	1	7.1
< 20% Weight loss	72 (8.7)	102	9.3	32 (5.6)	34	4.5
Missing	8 (8.5)	12	18.6	2 (2.6)	2	3.7
Dyspepsia						
>= 20% Weight loss	37 (9.5)	52	9.5	0		
< 20% Weight loss	91 (11.0)	119	10.9	20 (3.5)	27	3.5
Missing	7 (7.4)	8	12.4	3 (3.8)	3	5.6
Abdominal pain						
>= 20% Weight loss	46 (11.9)	57	10.4	0		
< 20% Weight loss	78 (9.5)	108	9.9	32 (5.6)	37	4.9
Missing	6 (6.4)	10	15.5	4 (5.1)	4	7.4
Eructation						
>= 20% Weight loss	35 (9.0)	43	7.8	0		
< 20% Weight loss	74 (9.0)	93	8.5	3 (0.5)	3	0.4
Missing	3 (3.2)	3	4.7	0		
Abdominal distension						
>= 20% Weight loss	28 (7.2)	33	6.0	0		
< 20% Weight loss	64 (7.8)	98	9.0	29 (5.1)	39	5.1
Missing	4 (4.3)	4	6.2	2 (2.6)	3	5.6
Abdominal discomfort						
>= 20% Weight loss	15 (3.9)	19	3.5	0		
< 20% Weight loss	37 (4.5)	54	4.9	7 (1.2)	7	0.9
Missing	4 (4.3)	6	9.3	2 (2.6)	2	3.7
Flatulence						
>= 20% Weight loss	19 (4.9)	24	4.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	44 (5.3)	57	5.2	20 (3.5)	21	2.8
Missing	2 (2.1)	3	4.7	1 (1.3)	1	1.9
Abdominal pain lower						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	3	0.4
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Retching						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Abnormal faeces						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Regurgitation						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Dysphagia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Faeces soft						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	3	0.3	5 (0.9)	5	0.7
Gastrointestinal pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	3	0.3	0		
Breath odour						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	1	(0.3)	2	0.4	0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Faeces discoloured								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	1	(0.1)	1	<0.1	2	(0.4)	2	0.3
Epigastric discomfort								
>= 20% Weight loss	0				0			
< 20% Weight loss	3	(0.4)	3	0.3	0			
Oesophageal pain								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Gastrointestinal sounds abnormal								
>= 20% Weight loss	0				0			
< 20% Weight loss	2	(0.2)	2	0.2	1	(0.2)	1	0.1
Abdominal tenderness								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Aerophagia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Faeces hard								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Gastrointestinal motility and defaecation conditions								
>= 20% Weight loss	192	(49.5)	379	69.0	2	(20.0)	2	14.1
< 20% Weight loss	393	(47.7)	833	76.2	153	(27.0)	224	29.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Missing	41	(43.6)	59	91.5	11	(14.1)	13	24.1
Diarrhoea								
>= 20% Weight loss	126	(32.5)	231	42.1	2	(20.0)	2	14.1
< 20% Weight loss	260	(31.6)	499	45.7	93	(16.4)	126	16.5
Missing	26	(27.7)	36	55.8	9	(11.5)	10	18.5
Constipation								
>= 20% Weight loss	100	(25.8)	123	22.4	0			
< 20% Weight loss	188	(22.8)	248	22.7	60	(10.6)	71	9.3
Missing	18	(19.1)	19	29.5	2	(2.6)	2	3.7
Gastrooesophageal reflux disease								
>= 20% Weight loss	17	(4.4)	19	3.5	0			
< 20% Weight loss	62	(7.5)	70	6.4	20	(3.5)	21	2.8
Missing	3	(3.2)	3	4.7	0			
Oesophageal achalasia								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	1	(1.1)	1	1.6	0			
Frequent bowel movements								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	4	(0.5)	4	0.4	2	(0.4)	2	0.3
Missing	0				1	(1.3)	1	1.9
Irritable bowel syndrome								
>= 20% Weight loss	0				0			
< 20% Weight loss	6	(0.7)	7	0.6	1	(0.2)	2	0.3
Dyschezia								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Bowel movement irregularity						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Defaecation urgency						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gastrointestinal hypermotility						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Infrequent bowel movements						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Impaired gastric emptying						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Change of bowel habit						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal motility disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal inflammatory conditions						
>= 20% Weight loss	18 (4.6)	25	4.6	1 (10.0)	1	7.1
< 20% Weight loss	52 (6.3)	68	6.2	9 (1.6)	10	1.3
Missing	1 (1.1)	1	1.6	2 (2.6)	2	3.7
Gastritis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	9 (2.3)	14	2.5	1 (10.0)	1	7.1
< 20% Weight loss	40 (4.9)	52	4.8	5 (0.9)	6	0.8
Missing	1 (1.1)	1	1.6	0		
Colitis						
>= 20% Weight loss	3 (0.8)	4	0.7	0		
< 20% Weight loss	4 (0.5)	5	0.5	0		
Missing	0			1 (1.3)	1	1.9
Reflux gastritis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Gastrointestinal inflammation						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Chronic gastritis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Duodenitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Oesophagitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Colitis ischaemic						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Enteritis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Crohn's disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Eosinophilic oesophagitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastroenteritis eosinophilic						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Epiploic appendagitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Inflammatory bowel disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gastrointestinal conditions NEC						
>= 20% Weight loss	12 (3.1)	14	2.5	0		
< 20% Weight loss	34 (4.1)	51	4.7	10 (1.8)	14	1.8
Missing	2 (2.1)	2	3.1	2 (2.6)	2	3.7
Food poisoning						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	10 (1.2)	10	0.9	3 (0.5)	5	0.7
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Hyperchlorhydria						
>= 20% Weight loss	4 (1.0)	6	1.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	16 (1.9)	31	2.8	2 (0.4)	4	0.5
Missing	0			1 (1.3)	1	1.9
Gastrointestinal disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	5	0.5	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Anal fistula						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Barrett's oesophagus						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Functional gastrointestinal disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastric mucosal hypertrophy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Dental and gingival conditions						
>= 20% Weight loss	9 (2.3)	10	1.8	1 (10.0)	1	7.1
< 20% Weight loss	15 (1.8)	19	1.7	26 (4.6)	29	3.8
Missing	3 (3.2)	3	4.7	2 (2.6)	2	3.7
Toothache						
>= 20% Weight loss	6 (1.5)	7	1.3	0		
< 20% Weight loss	8 (1.0)	10	0.9	16 (2.8)	17	2.2
Missing	3 (3.2)	3	4.7	1 (1.3)	1	1.9
Dental caries						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (10.0)	1	7.1
< 20% Weight loss	4 (0.5)	5	0.5	8 (1.4)	8	1.1
Missing	0			1 (1.3)	1	1.9
Gingival bleeding						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Gingival pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Tooth loss						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Gingival disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Noninfective gingivitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Periodontal disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tooth impacted						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Dental necrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Dental pulp disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Tooth disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Salivary gland conditions						
>= 20% Weight loss	12 (3.1)	12	2.2	0		
< 20% Weight loss	14 (1.7)	14	1.3	8 (1.4)	9	1.2
Missing	1 (1.1)	1	1.6	0		
Dry mouth						
>= 20% Weight loss	10 (2.6)	10	1.8	0		
< 20% Weight loss	14 (1.7)	14	1.3	7 (1.2)	8	1.1
Missing	1 (1.1)	1	1.6	0		
Salivary gland calculus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Salivary gland cyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Salivary gland enlargement						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gastrointestinal vascular conditions						
>= 20% Weight loss	12 (3.1)	13	2.4	2 (20.0)	2	14.1
< 20% Weight loss	16 (1.9)	17	1.6	3 (0.5)	3	0.4
Haemorrhoids						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	12 (3.1)	13	2.4	2 (20.0)	2	14.1
< 20% Weight loss	14 (1.7)	14	1.3	1 (0.2)	1	0.1
Haemorrhoidal haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	1 (0.2)	1	0.1
Haemorrhoids thrombosed						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Gastrointestinal haemorrhages NEC						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	7 (0.8)	8	0.7	6 (1.1)	7	0.9
Missing	2 (2.1)	2	3.1	0		
Rectal haemorrhage						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Haematochezia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Haematemesis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Lower gastrointestinal haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Melaena						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Upper gastrointestinal haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gastrointestinal ulceration and perforation						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	3 (0.4)	3	0.3	0		
Missing	1 (1.1)	1	1.6	0		
Large intestine perforation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Gastric ulcer						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	0			0		
Duodenal ulcer						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Oesophageal ulcer						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Peptic ulcer						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abdominal hernias and other abdominal wall conditions						
>= 20% Weight loss	3 (0.8)	4	0.7	0		
< 20% Weight loss	6 (0.7)	6	0.5	4 (0.7)	4	0.5
Hiatus hernia						
>= 20% Weight loss	3 (0.8)	4	0.7	0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1
Abdominal hernia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Umbilical hernia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Benign neoplasms gastrointestinal						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	8 (1.0)	8	0.7	4 (0.7)	4	0.5
Large intestine polyp						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	7 (0.8)	7	0.6	3 (0.5)	3	0.4
Gastric polyps						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Gastrointestinal stenosis and obstruction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Ileus						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Volvulus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Oesophageal stenosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Intestinal obstruction						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Oral soft tissue conditions						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	6 (0.7)	6	0.5	5 (0.9)	5	0.7
Missing	0			1 (1.3)	1	1.9
Cheilitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Lip disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Stomatitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Lip swelling						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	0		
Aphthous ulcer						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Mouth ulceration						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	2	(0.4)	2 0.3
Odynophagia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Paraesthesia oral						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	1	(0.2)	1 0.1
Oral mucosal eruption						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Anal and rectal conditions NEC						
>= 20% Weight loss	2	(0.5)	4 0.7	0		
< 20% Weight loss	5	(0.6)	5 0.5	0		
Proctalgia						
>= 20% Weight loss	2	(0.5)	3 0.5	0		
< 20% Weight loss	0			0		
Anal fissure						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	2	(0.2)	2 0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Anal pruritus						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Anorectal discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Rectal fissure						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Peritoneal and retroperitoneal conditions						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Pneumoperitoneum						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Diverticular disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	6 (0.7)	6	0.5	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Diverticulum						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	6 (0.7)	6	0.5	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Exocrine pancreas conditions						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	0				0			
Pancreatitis acute								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	0				0			
Malabsorption conditions								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Coeliac disease								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Tongue conditions								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Glossodynia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Infections and infestations								
>= 20% Weight loss	239	(61.6)	549	100.0	8	(80.0)	14	98.8
< 20% Weight loss	442	(53.6)	993	90.9	331	(58.4)	737	96.8
Missing	33	(35.1)	73	113.2	33	(42.3)	51	94.5
Infections - pathogen unspecified								
>= 20% Weight loss	210	(54.1)	436	79.4	8	(80.0)	10	70.5
< 20% Weight loss	387	(47.0)	760	69.6	281	(49.6)	563	73.9
Missing	29	(30.9)	51	79.1	25	(32.1)	37	68.6
Nasopharyngitis								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	91 (23.5)	176	32.1	2 (20.0)	2	14.1
< 20% Weight loss	180 (21.8)	293	26.8	123 (21.7)	206	27.1
Missing	10 (10.6)	11	17.1	8 (10.3)	8	14.8
Upper respiratory tract infection						
>= 20% Weight loss	42 (10.8)	52	9.5	3 (30.0)	4	28.2
< 20% Weight loss	65 (7.9)	97	8.9	70 (12.3)	103	13.5
Missing	7 (7.4)	9	14.0	7 (9.0)	9	16.7
Urinary tract infection						
>= 20% Weight loss	27 (7.0)	32	5.8	1 (10.0)	1	7.1
< 20% Weight loss	34 (4.1)	44	4.0	26 (4.6)	32	4.2
Missing	7 (7.4)	7	10.9	1 (1.3)	1	1.9
Gastroenteritis						
>= 20% Weight loss	29 (7.5)	36	6.6	0		
< 20% Weight loss	52 (6.3)	64	5.9	28 (4.9)	36	4.7
Missing	4 (4.3)	4	6.2	2 (2.6)	2	3.7
Sinusitis						
>= 20% Weight loss	26 (6.7)	28	5.1	1 (10.0)	1	7.1
< 20% Weight loss	44 (5.3)	55	5.0	34 (6.0)	38	5.0
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Bronchitis						
>= 20% Weight loss	10 (2.6)	10	1.8	1 (10.0)	1	7.1
< 20% Weight loss	33 (4.0)	36	3.3	21 (3.7)	24	3.2
Missing	4 (4.3)	6	9.3	3 (3.8)	3	5.6
Cystitis						
>= 20% Weight loss	5 (1.3)	6	1.1	0		
< 20% Weight loss	12 (1.5)	13	1.2	3 (0.5)	3	0.4
Missing	2 (2.1)	2	3.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Rhinitis						
>= 20% Weight loss	6 (1.5)	10	1.8	0		
< 20% Weight loss	12 (1.5)	14	1.3	9 (1.6)	14	1.8
Missing	1 (1.1)	1	1.6	0		
Laryngitis						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	6 (0.7)	6	0.5	4 (0.7)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Pneumonia						
>= 20% Weight loss	3 (0.8)	5	0.9	0		
< 20% Weight loss	7 (0.8)	8	0.7	8 (1.4)	8	1.1
Missing	1 (1.1)	1	1.6	0		
Pharyngitis						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	8 (1.0)	8	0.7	9 (1.6)	9	1.2
Conjunctivitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	3	0.4
Missing	1 (1.1)	1	1.6	0		
Vaginal infection						
>= 20% Weight loss	5 (1.3)	7	1.3	0		
< 20% Weight loss	6 (0.7)	6	0.5	0		
Tonsillitis						
>= 20% Weight loss	4 (1.0)	4	0.7	1 (10.0)	1	7.1
< 20% Weight loss	8 (1.0)	11	1.0	8 (1.4)	10	1.3
Missing	0			1 (1.3)	1	1.9
Acute sinusitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	7 (0.8)	7	0.6	8 (1.4)	9	1.2
Tooth infection						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	7 (0.8)	7	0.6	5 (0.9)	5	0.7
Tooth abscess						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	2 (0.2)	2	0.2	6 (1.1)	6	0.8
Missing	0			2 (2.6)	3	5.6
Ear infection						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	5 (0.6)	6	0.5	3 (0.5)	3	0.4
Pharyngotonsillitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Pyelonephritis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Lower respiratory tract infection						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	7 (0.8)	7	0.6	10 (1.8)	14	1.8
Missing	0			2 (2.6)	2	3.7
Otitis media						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Abdominal abscess						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Haematoma infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Parotitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Peritonitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Sepsis syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Pulpitis dental						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Folliculitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Eye infection						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	0		
Gastrointestinal infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	6	0.5	3 (0.5)	3	0.4
Gingivitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hordeolum						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Appendicitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	5 (0.6)	5	0.5	1 (0.2)	1	0.1
Omphalitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Breast abscess						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Infected bite						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Missing	0			1 (1.3)	1	1.9
Kidney infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Subcutaneous abscess						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Atypical pneumonia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Diarrhoea infectious						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	2	0.3
Periodontitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Postoperative wound infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Chronic sinusitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Eyelid infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Fracture infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Oral infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0		
Parasitic gastroenteritis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Paronychia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Skin infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Abdominal wall abscess						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Abscess						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Localised infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Otitis externa						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Abscess limb						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Appendicitis perforated						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Bartholinitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Carbuncle						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Device related infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Diverticulitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Endometritis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Epididymitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Groin abscess						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Large intestine infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Mastitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Nail infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Oophoritis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Osteomyelitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Perirectal abscess						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	2 0.2	0		
Prostate infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Purulence						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Respiratory tract infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Missing	0			1	(1.3)	1 1.9
Salpingitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Arthritis infective						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Cervicitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1	(1.3)	1 1.9
Empyema						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Gastric infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Infected dermal cyst						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Lymphangitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Neutropenic sepsis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Otitis media acute						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Peritonsillar abscess								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	0				1	(1.3)	1	1.9
Peritonsillitis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Root canal infection								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				2	(0.4)	2	0.3
Septic shock								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Tracheitis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Wound infection								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Viral infectious disorders								
>= 20% Weight loss	62	(16.0)	70	12.7	1	(10.0)	1	7.1
< 20% Weight loss	119	(14.4)	161	14.7	93	(16.4)	126	16.5
Missing	13	(13.8)	17	26.4	9	(11.5)	9	16.7
Influenza								
>= 20% Weight loss	27	(7.0)	31	5.6	1	(10.0)	1	7.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	56 (6.8)	75	6.9	59 (10.4)	75	9.8
Missing	6 (6.4)	6	9.3	3 (3.8)	3	5.6
Gastroenteritis viral						
>= 20% Weight loss	15 (3.9)	15	2.7	0		
< 20% Weight loss	24 (2.9)	26	2.4	13 (2.3)	14	1.8
Missing	3 (3.2)	3	4.7	1 (1.3)	1	1.9
Viral infection						
>= 20% Weight loss	3 (0.8)	4	0.7	0		
< 20% Weight loss	8 (1.0)	13	1.2	6 (1.1)	6	0.8
Missing	3 (3.2)	3	4.7	2 (2.6)	2	3.7
Herpes zoster						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	6 (0.7)	7	0.6	8 (1.4)	8	1.1
Missing	1 (1.1)	1	1.6	3 (3.8)	3	5.6
Gastroenteritis norovirus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	4	0.4	0		
Missing	1 (1.1)	1	1.6	0		
Oral herpes						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	3	0.3	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Gastrointestinal viral infection						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1
Dengue fever						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Viral upper respiratory tract infection						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	4 (0.7)	5	0.7
Oral viral infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Ear infection viral						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1
Herpes simplex						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Respiratory tract infection viral						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Viral pharyngitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Chronic hepatitis B						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Gastroenteritis astroviral						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			0		
Herpes virus infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	1	(0.2)	1 0.1
Cytomegalovirus infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Genital herpes zoster						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Hepatitis E						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Infectious mononucleosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	1	(0.2)	1 0.1
Papilloma viral infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Parainfluenzae virus infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Respiratory syncytial virus infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Varicella						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Vestibular neuronitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Viral sinusitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Bronchitis viral						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Conjunctivitis viral						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hand-foot-and-mouth disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Meningitis viral						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Viral rhinitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Bacterial infectious disorders						
>= 20% Weight loss	21 (5.4)	24	4.4	2 (20.0)	2	14.1
< 20% Weight loss	33 (4.0)	36	3.3	24 (4.2)	28	3.7
Missing	3 (3.2)	3	4.7	1 (1.3)	1	1.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Pharyngitis streptococcal						
>= 20% Weight loss	5 (1.3)	5	0.9	1 (10.0)	1	7.1
< 20% Weight loss	6 (0.7)	6	0.5	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Helicobacter infection						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Bacterial vaginosis						
>= 20% Weight loss	1 (0.3)	3	0.5	0		
< 20% Weight loss	3 (0.4)	4	0.4	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Cellulitis						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	5 (0.6)	5	0.5	7 (1.2)	8	1.1
Helicobacter gastritis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Ear infection bacterial						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Furuncle						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Staphylococcal infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Erysipelas						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Sinusitis bacterial						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Skin bacterial infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Tonsillitis bacterial						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Bacterial colitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Bacterial vulvovaginitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Genital infection bacterial						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Lyme disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pharyngitis bacterial						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Salmonellosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Syphilis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Typhoid fever						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Bacteriuria						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gastric ulcer helicobacter						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Listeriosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Staphylococcal sepsis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Streptococcal urinary tract infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Upper respiratory tract infection bacterial						
>= 20% Weight loss	0			1 (10.0)	1	7.1
< 20% Weight loss	0			0		
Fungal infectious disorders						
>= 20% Weight loss	14 (3.6)	18	3.3	1 (10.0)	1	7.1
< 20% Weight loss	29 (3.5)	33	3.0	18 (3.2)	19	2.5
Missing	2 (2.1)	2	3.1	3 (3.8)	4	7.4
Fungal infection						
>= 20% Weight loss	6 (1.5)	7	1.3	1 (10.0)	1	7.1
< 20% Weight loss	3 (0.4)	3	0.3	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Vulvovaginal mycotic infection						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	5 (0.6)	7	0.6	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Tinea infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Tinea pedis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	5	0.5	0		
Missing	0			1 (1.3)	1	1.9
Vulvovaginal candidiasis						
>= 20% Weight loss	1 (0.3)	3	0.5	0		
< 20% Weight loss	4 (0.5)	5	0.5	3 (0.5)	3	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Fungal skin infection						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Body tinea						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Dermatophytosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Onychomycosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	5	0.7
Missing	0			1 (1.3)	1	1.9
Skin candida						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Candida infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Dermatophytosis of nail						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tinea capitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tinea cruris						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Oral candidiasis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Otitis externa fungal						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Protozoal infectious disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Trichomoniasis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Toxoplasmosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Chlamydial infectious disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Chlamydial infection						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ectoparasitic disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Acarodermatitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Nervous system disorders								
>= 20% Weight loss	123	(31.7)	259	47.2	1	(10.0)	1	7.1
< 20% Weight loss	244	(29.6)	462	42.3	126	(22.2)	201	26.4
Missing	24	(25.5)	37	57.4	14	(17.9)	20	37.1
Headaches								
>= 20% Weight loss	67	(17.3)	152	27.7	1	(10.0)	1	7.1
< 20% Weight loss	145	(17.6)	272	24.9	82	(14.5)	111	14.6
Missing	17	(18.1)	27	41.9	6	(7.7)	6	11.1
Headache								
>= 20% Weight loss	61	(15.7)	126	22.9	1	(10.0)	1	7.1
< 20% Weight loss	123	(14.9)	239	21.9	73	(12.9)	97	12.7
Missing	14	(14.9)	22	34.1	6	(7.7)	6	11.1
Migraine								
>= 20% Weight loss	7	(1.8)	22	4.0	0			
< 20% Weight loss	22	(2.7)	27	2.5	9	(1.6)	11	1.4
Missing	3	(3.2)	3	4.7	0			
Tension headache								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Missing	1	(1.1)	1	1.6	0			
Sinus headache								
>= 20% Weight loss	0				0			
< 20% Weight loss	4	(0.5)	4	0.4	1	(0.2)	1	0.1
Missing	1	(1.1)	1	1.6	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Migraine with aura						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Occipital neuralgia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Neurological disorders NEC						
>= 20% Weight loss	64 (16.5)	88	16.0	0		
< 20% Weight loss	109 (13.2)	152	13.9	43 (7.6)	60	7.9
Missing	8 (8.5)	8	12.4	4 (5.1)	8	14.8
Dizziness						
>= 20% Weight loss	37 (9.5)	51	9.3	0		
< 20% Weight loss	57 (6.9)	75	6.9	21 (3.7)	29	3.8
Missing	4 (4.3)	4	6.2	2 (2.6)	6	11.1
Dysgeusia						
>= 20% Weight loss	5 (1.3)	7	1.3	0		
< 20% Weight loss	12 (1.5)	16	1.5	3 (0.5)	10	1.3
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Paraesthesia						
>= 20% Weight loss	6 (1.5)	7	1.3	0		
< 20% Weight loss	7 (0.8)	10	0.9	5 (0.9)	5	0.7
Syncope						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	5 (0.6)	5	0.5	2 (0.4)	2	0.3
Lethargy						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	3	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Taste disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	8 (1.0)	10	0.9	1 (0.2)	1	0.1
Burning sensation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Hypoaesthesia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	2 (0.4)	2	0.3
Ageusia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Somnolence						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	6 (0.7)	7	0.6	0		
Missing	0			1 (1.3)	1	1.9
Neuralgia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	2 (0.4)	2	0.3
Dizziness postural						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hyperaesthesia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.4)	5	0.5	0		
Balance disorder						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Allodynia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Presyncope						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Dysaesthesia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Dysarthria						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Aphasia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hyporeflexia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Loss of consciousness						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Restless legs syndrome						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	2	0.2	2 (0.4)	2	0.3
Sensory disturbance						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Vertigo CNS origin						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Sensory loss						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Spinal cord and nerve root disorders						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	14 (1.7)	16	1.5	13 (2.3)	13	1.7
Missing	0			1 (1.3)	1	1.9
Sciatica						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	10 (1.2)	12	1.1	7 (1.2)	7	0.9
Missing	0			1 (1.3)	1	1.9
Lumbar radiculopathy						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Spinal cord compression						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Cervicobrachial syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	4	0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cervical radiculopathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Lumbosacral radiculopathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Peripheral neuropathies						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	5 (0.6)	6	0.5	7 (1.2)	8	1.1
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Peripheral sensory neuropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Carpal tunnel syndrome						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	3	0.3	3 (0.5)	3	0.4
Neuropathy peripheral						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Nerve compression						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Peroneal nerve palsy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Radial nerve compression						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Mental impairment disorders						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	3	0.4
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Memory impairment						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Amnesia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Dementia Alzheimer's type						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Disturbance in attention						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	3	0.4
Missing	0			1 (1.3)	1	1.9
Sleep disturbances (incl subtypes)						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Poor quality sleep						
>= 20% Weight loss	3 (0.8)	3	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Movement disorders (incl parkinsonism)						
>= 20% Weight loss	0			0		
< 20% Weight loss	6 (0.7)	6	0.5	1 (0.2)	2	0.3
Missing	0			1 (1.3)	1	1.9
Tremor						
>= 20% Weight loss	0			0		
< 20% Weight loss	5 (0.6)	5	0.5	1 (0.2)	2	0.3
Missing	0			1 (1.3)	1	1.9
Essential tremor						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cranial nerve disorders (excl neoplasms)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Cranial nerve disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Anosmia						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Parosmia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Neurological disorders of the eye						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Visual field defect						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Central nervous system vascular disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Cerebral infarction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ischaemic stroke						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Increased intracranial pressure and hydrocephalus						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Idiopathic intracranial hypertension						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Neuromuscular disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Autonomic nervous system imbalance						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Demyelinating disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	0				1	(1.3)	1	1.9
Multiple sclerosis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	0				1	(1.3)	1	1.9
Seizures (incl subtypes)								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				2	(0.4)	2	0.3
Partial seizures								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Psychogenic seizure								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Musculoskeletal and connective tissue disorders								
>= 20% Weight loss	100	(25.8)	170	31.0	4	(40.0)	7	49.4
< 20% Weight loss	225	(27.3)	370	33.9	172	(30.3)	284	37.3
Missing	13	(13.8)	18	27.9	10	(12.8)	13	24.1
Musculoskeletal and connective tissue disorders NEC								
>= 20% Weight loss	56	(14.4)	68	12.4	1	(10.0)	2	14.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	122 (14.8)	166	15.2	94 (16.6)	126	16.5
Missing	9 (9.6)	10	15.5	4 (5.1)	4	7.4
Back pain						
>= 20% Weight loss	36 (9.3)	40	7.3	0		
< 20% Weight loss	67 (8.1)	76	7.0	52 (9.2)	54	7.1
Missing	4 (4.3)	5	7.8	2 (2.6)	2	3.7
Pain in extremity						
>= 20% Weight loss	13 (3.4)	13	2.4	0		
< 20% Weight loss	29 (3.5)	33	3.0	22 (3.9)	26	3.4
Missing	2 (2.1)	2	3.1	2 (2.6)	2	3.7
Musculoskeletal pain						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	25 (3.0)	25	2.3	16 (2.8)	18	2.4
Missing	1 (1.1)	1	1.6	0		
Neck pain						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	13 (1.6)	15	1.4	9 (1.6)	9	1.2
Missing	1 (1.1)	1	1.6	0		
Musculoskeletal chest pain						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Musculoskeletal stiffness						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Plantar fasciitis						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	2	14.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.2)	2	0.2	5 (0.9)	5	0.7
Flank pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Axillary mass						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Dupuytren's contracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Musculoskeletal discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Groin pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Limb mass						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	2	0.3
Muscle contracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Neck mass						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Joint disorders						
>= 20% Weight loss	37 (9.5)	47	8.6	2 (20.0)	3	21.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	92 (11.2)	117	10.7	67 (11.8)	84	11.0
Missing	4 (4.3)	5	7.8	6 (7.7)	7	13.0
Arthralgia						
>= 20% Weight loss	18 (4.6)	20	3.6	0		
< 20% Weight loss	60 (7.3)	68	6.2	42 (7.4)	45	5.9
Missing	3 (3.2)	4	6.2	1 (1.3)	2	3.7
Osteoarthritis						
>= 20% Weight loss	9 (2.3)	11	2.0	1 (10.0)	1	7.1
< 20% Weight loss	14 (1.7)	17	1.6	16 (2.8)	18	2.4
Missing	0			1 (1.3)	1	1.9
Arthritis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Spinal osteoarthritis						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	7 (0.8)	8	0.7	0		
Rotator cuff syndrome						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Joint swelling						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	6 (0.7)	6	0.5	2 (0.4)	2	0.3
Missing	0			2 (2.6)	2	3.7
Joint stiffness						
>= 20% Weight loss	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Vertebral foraminal stenosis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	2	(0.2)	3 0.3	0		
Facet joint syndrome						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	2 0.2	0		
Periarthritis						
>= 20% Weight loss	1	(0.3)	1 0.2	1	(10.0)	2 14.1
< 20% Weight loss	0			0		
Spondylitis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	0			0		
Arthropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	2 0.2	1	(0.2)	1 0.1
Vertebral osteophyte						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Chondromalacia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Haemarthrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Joint noise						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Joint range of motion decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Joint space narrowing						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Polyarthritis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Rheumatoid arthritis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Spondyloarthropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Muscle disorders						
>= 20% Weight loss	20 (5.2)	21	3.8	0		
< 20% Weight loss	35 (4.2)	40	3.7	23 (4.1)	29	3.8
Missing	3 (3.2)	3	4.7	0		
Myalgia						
>= 20% Weight loss	8 (2.1)	8	1.5	0		
< 20% Weight loss	14 (1.7)	17	1.6	8 (1.4)	13	1.7
Missing	1 (1.1)	1	1.6	0		
Muscle spasms						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	13 (1.6)	13	1.2	10 (1.8)	11	1.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Fibromyalgia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	3 (0.5)	3	0.4
Missing	1 (1.1)	1	1.6	0		
Muscular weakness						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Muscle disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Muscle fatigue						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Muscle tightness						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Myofascial pain syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Muscle twitching						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Myalgia intercostal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Myosclerosis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Torticollis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Tendon, ligament and cartilage disorders						
>= 20% Weight loss	9 (2.3)	9	1.6	0		
< 20% Weight loss	16 (1.9)	18	1.6	13 (2.3)	15	2.0
Tendonitis						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	8 (1.0)	9	0.8	9 (1.6)	11	1.4
Tenosynovitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Costochondritis						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Osteochondrosis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Trigger finger						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Tendon disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Posterior tibial tendon dysfunction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tendon discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tendon pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)						
>= 20% Weight loss	6 (1.5)	10	1.8	1 (10.0)	1	7.1
< 20% Weight loss	13 (1.6)	14	1.3	10 (1.8)	12	1.6
Intervertebral disc protrusion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	7 (0.8)	7	0.6	4 (0.7)	5	0.7
Intervertebral disc degeneration						
>= 20% Weight loss	1 (0.3)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	2 (0.4)	2	0.3
Scoliosis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Intervertebral disc displacement						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Kyphoscoliosis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Spinal stenosis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Spondylolisthesis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Cervical spinal stenosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Finger deformity						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Foot deformity						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Intervertebral disc annular tear						
>= 20% Weight loss	0			1 (10.0)	1	7.1
< 20% Weight loss	0			0		
Kyphosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Synovial and bursal disorders						
>= 20% Weight loss	8 (2.1)	8	1.5	0		
< 20% Weight loss	8 (1.0)	8	0.7	5 (0.9)	5	0.7
Bursitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	6 (0.7)	6	0.5	3 (0.5)	3	0.4
Synovial cyst						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Synovitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Bursal fluid accumulation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Bone disorders (excl congenital and fractures)						
>= 20% Weight loss	5 (1.3)	6	1.1	1 (10.0)	1	7.1
< 20% Weight loss	6 (0.7)	6	0.5	12 (2.1)	12	1.6
Missing	0			1 (1.3)	1	1.9
Osteopenia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Bone cyst						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	0			0		
Coccydynia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Osteoporosis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			3	(0.5)	3 0.4
Pain in jaw						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	2	(0.4)	2 0.3
Exostosis						
>= 20% Weight loss	0			1	(10.0)	1 7.1
< 20% Weight loss	1	(0.1)	1 <0.1	1	(0.2)	1 0.1
Missing	0			1	(1.3)	1 1.9
Metatarsalgia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	2	(0.4)	2 0.3
Osteonecrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Pubic pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Connective tissue disorders (excl congenital)						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	1 <0.1	1	(0.2)	1 0.1
Missing	0			1	(1.3)	1 1.9
Myofascitis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	0			0		
Sjogren's syndrome						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Systemic lupus erythematosus								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Systemic scleroderma								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	0				1	(1.3)	1	1.9
General disorders and administration site conditions								
>= 20% Weight loss	94	(24.2)	144	26.2	1	(10.0)	1	7.1
< 20% Weight loss	180	(21.8)	296	27.1	118	(20.8)	206	27.1
Missing	17	(18.1)	25	38.8	12	(15.4)	15	27.8
General system disorders NEC								
>= 20% Weight loss	73	(18.8)	103	18.8	0			
< 20% Weight loss	137	(16.6)	202	18.5	78	(13.8)	104	13.7
Missing	15	(16.0)	19	29.5	8	(10.3)	9	16.7
Fatigue								
>= 20% Weight loss	31	(8.0)	42	7.6	0			
< 20% Weight loss	66	(8.0)	71	6.5	25	(4.4)	26	3.4
Missing	7	(7.4)	7	10.9	3	(3.8)	3	5.6
Asthenia								
>= 20% Weight loss	9	(2.3)	12	2.2	0			
< 20% Weight loss	24	(2.9)	39	3.6	10	(1.8)	11	1.4
Missing	2	(2.1)	2	3.1	1	(1.3)	1	1.9
Early satiety								

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	10 (2.6)	10	1.8	0		
< 20% Weight loss	13 (1.6)	13	1.2	2 (0.4)	2	0.3
Missing	3 (3.2)	3	4.7	0		
Pain						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	13 (1.6)	15	1.4	6 (1.1)	6	0.8
Missing	2 (2.1)	2	3.1	1 (1.3)	1	1.9
Malaise						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	11 (1.3)	14	1.3	4 (0.7)	5	0.7
Missing	2 (2.1)	2	3.1	0		
Influenza like illness						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	13 (1.6)	14	1.3	12 (2.1)	12	1.6
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Non-cardiac chest pain						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Missing	2 (2.1)	2	3.1	1 (1.3)	1	1.9
Chest discomfort						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	7 (0.8)	7	0.6	1 (0.2)	2	0.3
Missing	0			1 (1.3)	1	1.9
Chills						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	2 (0.4)	2	0.3
Hunger						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	3	0.4
Chest pain						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	0			7 (1.2)	7	0.9
Oedema peripheral						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	8 (1.4)	8	1.1
Feeling hot						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Ill-defined disorder						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Swelling face						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Feeling cold						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Hernia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Thirst						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Axillary pain						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Fat tissue increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hangover						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Pseudocyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Sense of oppression						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	0			0		
Peripheral swelling						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Sensation of foreign body						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Swelling						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Crying						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Inflammation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	1 (0.2)	1	0.1
Sluggishness						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Facial pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Granuloma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gravitational oedema						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Temperature intolerance						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Administration site reactions						
>= 20% Weight loss	22 (5.7)	31	5.6	0		
< 20% Weight loss	40 (4.9)	64	5.9	41 (7.2)	77	10.1
Missing	3 (3.2)	4	6.2	3 (3.8)	5	9.3
Injection site pain						
>= 20% Weight loss	6 (1.5)	7	1.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	11 (1.3)	15	1.4	16 (2.8)	21	2.8
Missing	2 (2.1)	2	3.1	0		
Injection site bruising						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	21 (2.5)	24	2.2	23 (4.1)	31	4.1
Missing	0			3 (3.8)	3	5.6
Injection site pruritus						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	6 (0.7)	6	0.5	1 (0.2)	1	0.1
Injection site haematoma						
>= 20% Weight loss	1 (0.3)	5	0.9	0		
< 20% Weight loss	1 (0.1)	2	0.2	4 (0.7)	12	1.6
Missing	1 (1.1)	1	1.6	0		
Injection site paraesthesia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Injection site erythema						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Injection site mass						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Injection site reaction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Application site haematoma						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Injection site inflammation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	3	0.3	0		
Infusion site extravasation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Injection site induration						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Vessel puncture site bruise						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Injection site haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Injection site swelling						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	2	3.7
Injection site urticaria						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Vessel puncture site rash						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Application site bruise						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Puncture site pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	2	0.3
Body temperature conditions						
>= 20% Weight loss	5 (1.3)	6	1.1	0		
< 20% Weight loss	21 (2.5)	26	2.4	16 (2.8)	20	2.6
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Pyrexia						
>= 20% Weight loss	5 (1.3)	6	1.1	0		
< 20% Weight loss	21 (2.5)	26	2.4	16 (2.8)	20	2.6
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Tissue disorders NEC						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	1 (0.1)	1	<0.1	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Nodule						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Cyst						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Dysplasia						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Fat necrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hyperplasia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Complications associated with device						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Injury associated with device						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	0			0		
Vascular stent occlusion						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Therapeutic and nontherapeutic effects (excl toxicity)						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Withdrawal syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Skin and subcutaneous tissue disorders						
>= 20% Weight loss	66 (17.0)	86	15.7	1 (10.0)	1	7.1
< 20% Weight loss	112 (13.6)	150	13.7	74 (13.1)	95	12.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	10 (10.6)	13	20.2	0		
Epidermal and dermal conditions						
>= 20% Weight loss	41 (10.6)	46	8.4	1 (10.0)	1	7.1
< 20% Weight loss	59 (7.2)	75	6.9	51 (9.0)	64	8.4
Missing	5 (5.3)	8	12.4	0		
Rash						
>= 20% Weight loss	12 (3.1)	12	2.2	0		
< 20% Weight loss	11 (1.3)	12	1.1	17 (3.0)	23	3.0
Missing	3 (3.2)	6	9.3	0		
Eczema						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	7 (0.8)	7	0.6	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Pruritus						
>= 20% Weight loss	7 (1.8)	8	1.5	0		
< 20% Weight loss	10 (1.2)	10	0.9	6 (1.1)	6	0.8
Dry skin						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	6 (0.7)	6	0.5	3 (0.5)	3	0.4
Blister						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Dermatitis contact						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	1 (0.1)	2	0.2	4 (0.7)	4	0.5
Skin burning sensation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	6 (0.7)	12	1.1	2 (0.4)	2	0.3
Psoriasis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin lesion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Dermatitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Pain of skin						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Skin irritation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Decubitus ulcer						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Dermatitis allergic						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	2	0.2	1 (0.2)	1	0.1
Erythema						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (10.0)	1	7.1
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Rash pruritic						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Papule						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Perioral dermatitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Pityriasis rosea						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Prurigo						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Rash maculo-papular						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Dermatitis atopic						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Macule						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin discolouration						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Skin odour abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Xanthelasma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Drug eruption						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Photosensitivity reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Rash erythematous						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Rash macular						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Skin reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Skin appendage conditions						
>= 20% Weight loss	29 (7.5)	33	6.0	0		
< 20% Weight loss	48 (5.8)	54	4.9	19 (3.4)	21	2.8
Missing	5 (5.3)	5	7.8	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Alopecia						
>= 20% Weight loss	24 (6.2)	25	4.6	0		
< 20% Weight loss	27 (3.3)	28	2.6	5 (0.9)	5	0.7
Missing	2 (2.1)	2	3.1	0		
Hyperhidrosis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	5	0.5	8 (1.4)	8	1.1
Missing	2 (2.1)	2	3.1	0		
Hirsutism						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	2	0.2	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Acne						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Ingrowing nail						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	2	0.3
Hair growth abnormal						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Miliaria						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cold sweat						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hypertrichosis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Night sweats						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hidradenitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Rosacea						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	3	0.3	2 (0.4)	2	0.3
Diffuse alopecia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Nail bed inflammation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Nail discolouration						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Onychoclasis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Angioedema and urticaria						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	10 (1.2)	10	0.9	6 (1.1)	6	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Urticaria						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	9 (1.1)	9	0.8	5 (0.9)	5	0.7
Cold urticaria						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Angioedema						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Cornification and dystrophic skin disorders						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	6 (0.7)	7	0.6	0		
Actinic keratosis						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Hyperkeratosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Lichenoid keratosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Skin striae						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pigmentation disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.2)	2	0.2	0		
Ephelides						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin hyperpigmentation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cutaneous neoplasms benign						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Dermal cyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Skin vascular abnormalities						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Ecchymosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Skin and subcutaneous tissue disorders NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Erythema nodosum						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Skin ulcer						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Metabolism and nutrition disorders								
>= 20% Weight loss	70	(18.0)	98	17.8	0			
< 20% Weight loss	121	(14.7)	156	14.3	77	(13.6)	102	13.4
Missing	8	(8.5)	13	20.2	6	(7.7)	6	11.1
Appetite and general nutritional disorders								
>= 20% Weight loss	58	(14.9)	73	13.3	0			
< 20% Weight loss	76	(9.2)	91	8.3	27	(4.8)	35	4.6
Missing	7	(7.4)	8	12.4	1	(1.3)	1	1.9
Decreased appetite								
>= 20% Weight loss	55	(14.2)	64	11.7	0			
< 20% Weight loss	65	(7.9)	71	6.5	21	(3.7)	25	3.3
Missing	4	(4.3)	4	6.2	1	(1.3)	1	1.9
Food craving								
>= 20% Weight loss	3	(0.8)	3	0.5	0			
< 20% Weight loss	4	(0.5)	4	0.4	2	(0.4)	2	0.3
Missing	1	(1.1)	1	1.6	0			
Hyperphagia								
>= 20% Weight loss	3	(0.8)	3	0.5	0			
< 20% Weight loss	3	(0.4)	3	0.3	2	(0.4)	4	0.5
Missing	1	(1.1)	2	3.1	0			
Malnutrition								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Increased appetite						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	6	0.5	2 (0.4)	2	0.3
Food aversion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	5	0.5	0		
Lack of satiety						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Lipid metabolism disorders						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	15 (1.8)	15	1.4	18 (3.2)	19	2.5
Missing	1 (1.1)	1	1.6	2 (2.6)	2	3.7
Dyslipidaemia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	7 (0.8)	7	0.6	9 (1.6)	10	1.3
Missing	1 (1.1)	1	1.6	0		
Hypercholesterolaemia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	5 (0.9)	5	0.7
Missing	0			1 (1.3)	1	1.9
Hypertriglyceridaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Cholesterosis						
>= 20% Weight loss	1 (0.3)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	0				0			
Hyperlipidaemia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	3	(0.5)	3	0.4
Missing	0				1	(1.3)	1	1.9
Vitamin related disorders								
>= 20% Weight loss	7	(1.8)	8	1.5	0			
< 20% Weight loss	15	(1.8)	20	1.8	9	(1.6)	11	1.4
Missing	0				1	(1.3)	1	1.9
Vitamin D deficiency								
>= 20% Weight loss	5	(1.3)	5	0.9	0			
< 20% Weight loss	12	(1.5)	12	1.1	7	(1.2)	7	0.9
Missing	0				1	(1.3)	1	1.9
Vitamin B12 deficiency								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	4	(0.5)	4	0.4	0			
Vitamin B complex deficiency								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				2	(0.4)	2	0.3
Folate deficiency								
>= 20% Weight loss	0				0			
< 20% Weight loss	2	(0.2)	2	0.2	2	(0.4)	2	0.3
Vitamin A deficiency								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Vitamin B2 deficiency								
>= 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Electrolyte and fluid balance conditions						
>= 20% Weight loss	1 (0.3)	3	0.5	0		
< 20% Weight loss	7 (0.8)	7	0.6	6 (1.1)	6	0.8
Missing	1 (1.1)	2	3.1	0		
Hyponatraemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Dehydration						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Hypokalaemia						
>= 20% Weight loss	1 (0.3)	3	0.5	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Hyperkalaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Electrolyte imbalance						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Polydipsia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Fluid retention						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Iron and trace metal metabolism disorders						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Iron deficiency						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Glucose metabolism disorders (incl diabetes mellitus)						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	7 (0.8)	14	1.3	20 (3.5)	24	3.2
Missing	0			1 (1.3)	1	1.9
Hypoglycaemia						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	10	0.9	5 (0.9)	7	0.9
Glucose tolerance impaired						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	4 (0.7)	4	0.5
Postprandial hypoglycaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Type 2 diabetes mellitus						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	1	(0.1)	1 <0.1	5	(0.9)	6 0.8
Missing	0			1	(1.3)	1 1.9
Diabetes mellitus						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Hyperglycaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2	(0.4)	2 0.3
Impaired fasting glucose						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			3	(0.5)	3 0.4
Insulin resistance						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Protein and amino acid metabolism disorders NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1	(1.1)	1 1.6	0		
Hypoalbuminaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1	(1.1)	1 1.6	0		
Food intolerance syndromes						
>= 20% Weight loss	3	(0.8)	3 0.5	0		
< 20% Weight loss	0			0		
Dairy intolerance						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Food intolerance						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Lactose intolerance						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Purine and pyrimidine metabolism disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	5	0.5	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Gout						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	5	0.5	2 (0.4)	2	0.3
Missing	0			1 (1.3)	1	1.9
Hyperuricaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Metabolism disorders NEC						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hyperlipasaemia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Bone, calcium, magnesium and phosphorus metabolism disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Hypomagnesaemia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Injury, poisoning and procedural complications								
>= 20% Weight loss	61	(15.7)	74	13.5	2	(20.0)	2	14.1
< 20% Weight loss	119	(14.4)	181	16.6	109	(19.2)	161	21.1
Missing	8	(8.5)	9	14.0	10	(12.8)	13	24.1
Injuries NEC								
>= 20% Weight loss	42	(10.8)	48	8.7	1	(10.0)	1	7.1
< 20% Weight loss	80	(9.7)	115	10.5	86	(15.2)	118	15.5
Missing	4	(4.3)	5	7.8	9	(11.5)	11	20.4
Ligament sprain								
>= 20% Weight loss	4	(1.0)	5	0.9	1	(10.0)	1	7.1
< 20% Weight loss	15	(1.8)	16	1.5	16	(2.8)	17	2.2
Missing	2	(2.1)	3	4.7	2	(2.6)	2	3.7
Fall								
>= 20% Weight loss	4	(1.0)	4	0.7	0			
< 20% Weight loss	15	(1.8)	15	1.4	12	(2.1)	19	2.5
Muscle strain								
>= 20% Weight loss	4	(1.0)	4	0.7	0			
< 20% Weight loss	13	(1.6)	14	1.3	11	(1.9)	11	1.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	0			4 (5.1)	4	7.4
Arthropod bite						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	5 (0.6)	5	0.5	7 (1.2)	7	0.9
Missing	1 (1.1)	1	1.6	0		
Contusion						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	11 (1.3)	14	1.3	15 (2.6)	19	2.5
Skin laceration						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	4 (0.5)	4	0.4	8 (1.4)	9	1.2
Limb injury						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Muscle injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Tooth fracture						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Arthropod sting						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	5	0.5	2 (0.4)	2	0.3
Skin abrasion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	4 (0.5)	7	0.6	3 (0.5)	3	0.4
Animal bite						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Concussion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Epicondylitis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Ligament rupture						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Back injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Muscle rupture						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Road traffic accident						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Wound						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Bone contusion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Eyelid contusion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Face injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Head injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Tendon injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Eye burns						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Eyelid injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Foreign body in eye						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Ligament injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Musculoskeletal injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Nerve injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Post-traumatic neck syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Missing	0			1	(1.3)	1 1.9
Post-traumatic pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Skeletal injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Soft tissue foreign body						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Subdural haematoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Chest injury						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Corneal abrasion						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Eye injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Gun shot wound						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9
Post concussion syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Scar						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Tendon rupture						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	3	0.4
Bone and joint injuries						
>= 20% Weight loss	8 (2.1)	9	1.6	1 (10.0)	1	7.1
< 20% Weight loss	25 (3.0)	28	2.6	21 (3.7)	22	2.9
Missing	2 (2.1)	2	3.1	0		
Joint injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Radius fracture						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Foot fracture						
>= 20% Weight loss	2 (0.5)	3	0.5	1 (10.0)	1	7.1
< 20% Weight loss	3 (0.4)	4	0.4	4 (0.7)	4	0.5
Hand fracture						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Joint dislocation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Meniscus injury						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	4	0.4	4 (0.7)	5	0.7
Rib fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Ankle fracture						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Facial bones fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Femur fracture						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Fractured coccyx						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Spinal compression fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Stress fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Thoracic vertebral fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Tibia fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Upper limb fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Wrist fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Fibula fracture						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Torus fracture						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Procedural related injuries and complications NEC						
>= 20% Weight loss	9 (2.3)	9	1.6	0		
< 20% Weight loss	17 (2.1)	25	2.3	9 (1.6)	11	1.4
Missing	1 (1.1)	1	1.6	2 (2.6)	2	3.7
Procedural pain						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	8 (1.0)	9	0.8	6 (1.1)	8	1.1
Missing	0			1 (1.3)	1	1.9
Injection related reaction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Missing	1 (1.1)	1	1.6	0		
Post procedural complication						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	3	0.3	0		
Administration related reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Post procedural haemorrhage						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Suture related complication						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Procedural nausea						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Anaemia postoperative						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Anaphylactic transfusion reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Post procedural constipation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Procedural haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Urinary retention postoperative						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Vaccination complication						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Procedural vomiting						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9
Seroma						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Medication errors and other product use errors and issues						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	7 (0.8)	7	0.6	2 (0.4)	3	0.4
Accidental overdose						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	2 (0.4)	3	0.4
Incorrect dose administered						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Medication error						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Overdoses and underdoses NEC						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Overdose						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Injuries by physical agents						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	5 (0.9)	5	0.7
Sunburn						
>= 20% Weight loss	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0		
Heat exhaustion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Heat illness						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hypobarism						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Thermal burn						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Burns second degree						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Exposures, chemical injuries and poisoning						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Exposure to toxic agent						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Reactive gastropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
>= 20% Weight loss	53	(13.7)	63	11.5	1	(10.0)	1	7.1
< 20% Weight loss	110	(13.3)	146	13.4	95	(16.8)	123	16.2
Missing	10	(10.6)	16	24.8	8	(10.3)	10	18.5
Respiratory tract signs and symptoms								
>= 20% Weight loss	27	(7.0)	32	5.8	1	(10.0)	1	7.1
< 20% Weight loss	44	(5.3)	45	4.1	32	(5.6)	36	4.7
Missing	4	(4.3)	4	6.2	0			
Oropharyngeal pain								
>= 20% Weight loss	23	(5.9)	28	5.1	1	(10.0)	1	7.1
< 20% Weight loss	23	(2.8)	23	2.1	22	(3.9)	25	3.3
Missing	2	(2.1)	2	3.1	0			
Catarrh								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Missing	1	(1.1)	1	1.6	0			
Yawning								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	1	(1.1)	1	1.6	0			
Upper respiratory tract inflammation								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	3	(0.4)	4	0.4	4	(0.7)	4	0.5
Rhinorrhoea								
>= 20% Weight loss	0				0			
< 20% Weight loss	6	(0.7)	6	0.5	1	(0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hiccups						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Upper-airway cough syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Pleuritic pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Dysphonia						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Diaphragmalgia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Oropharyngeal discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Paranasal sinus discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Sinus pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Upper respiratory tract congestion						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Respiratory disorders NEC						
>= 20% Weight loss	16 (4.1)	17	3.1	0		
< 20% Weight loss	41 (5.0)	47	4.3	48 (8.5)	52	6.8
Missing	4 (4.3)	6	9.3	3 (3.8)	4	7.4
Cough						
>= 20% Weight loss	12 (3.1)	13	2.4	0		
< 20% Weight loss	27 (3.3)	30	2.7	32 (5.6)	33	4.3
Missing	1 (1.1)	2	3.1	1 (1.3)	2	3.7
Dyspnoea						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	8 (1.4)	8	1.1
Missing	1 (1.1)	1	1.6	0		
Sleep apnoea syndrome						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	4 (0.7)	4	0.5
Missing	1 (1.1)	1	1.6	0		
Dyspnoea exertional						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Hyperventilation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Respiratory disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	3 (0.5)	3	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	0			1 (1.3)	1	1.9
Productive cough						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Haemoptysis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Respiratory tract congestion						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Acute respiratory failure						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Pulmonary mass						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Upper respiratory tract disorders (excl infections)						
>= 20% Weight loss	8 (2.1)	8	1.5	0		
< 20% Weight loss	40 (4.9)	41	3.8	15 (2.6)	18	2.4
Missing	3 (3.2)	4	6.2	3 (3.8)	3	5.6
Sinus congestion						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	8 (1.0)	8	0.7	5 (0.9)	7	0.9
Missing	2 (2.1)	2	3.1	0		
Rhinitis allergic						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	9 (1.1)	9	0.8	5 (0.9)	6	0.8
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Nasal congestion						
>= 20% Weight loss	0			0		
< 20% Weight loss	11 (1.3)	11	1.0	4 (0.7)	4	0.5
Missing	0			2 (2.6)	2	3.7
Tonsillar hypertrophy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Epistaxis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	0		
Paranasal sinus hypersecretion						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Paranasal cyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Nasal polyps						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Nasal septum deviation						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Nasal dryness						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Vocal cord polyp								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Nasal adhesions								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Bronchial disorders (excl neoplasms)								
>= 20% Weight loss	4	(1.0)	4	0.7	0			
< 20% Weight loss	9	(1.1)	9	0.8	10	(1.8)	13	1.7
Missing	1	(1.1)	1	1.6	3	(3.8)	3	5.6
Asthma								
>= 20% Weight loss	4	(1.0)	4	0.7	0			
< 20% Weight loss	6	(0.7)	6	0.5	7	(1.2)	9	1.2
Missing	1	(1.1)	1	1.6	2	(2.6)	2	3.7
Chronic obstructive pulmonary disease								
>= 20% Weight loss	0				0			
< 20% Weight loss	2	(0.2)	2	0.2	1	(0.2)	1	0.1
Missing	0				1	(1.3)	1	1.9
Wheezing								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Allergic bronchitis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	2	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Lower respiratory tract disorders (excl obstruction and infection)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Atelectasis						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Pulmonary fibrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pulmonary vascular disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Pulmonary embolism						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Pleural disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Pleural effusion						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Pleurisy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Psychiatric disorders						
>= 20% Weight loss	35 (9.0)	49	8.9	1 (10.0)	1	7.1
< 20% Weight loss	82 (10.0)	101	9.2	76 (13.4)	106	13.9
Missing	7 (7.4)	10	15.5	6 (7.7)	6	11.1
Anxiety disorders and symptoms						
>= 20% Weight loss	15 (3.9)	15	2.7	1 (10.0)	1	7.1
< 20% Weight loss	27 (3.3)	29	2.7	28 (4.9)	29	3.8
Missing	4 (4.3)	4	6.2	2 (2.6)	2	3.7
Anxiety						
>= 20% Weight loss	9 (2.3)	9	1.6	1 (10.0)	1	7.1
< 20% Weight loss	21 (2.5)	22	2.0	19 (3.4)	19	2.5
Missing	2 (2.1)	2	3.1	0		
Stress						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	3 (0.4)	3	0.3	6 (1.1)	6	0.8
Missing	1 (1.1)	1	1.6	0		
Burnout syndrome						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Panic attack						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Acute stress disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Nervousness						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Post-traumatic stress disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Agitation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			2 (2.6)	2	3.7
Generalised anxiety disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Depressed mood disorders and disturbances						
>= 20% Weight loss	7 (1.8)	10	1.8	0		
< 20% Weight loss	23 (2.8)	25	2.3	25 (4.4)	27	3.5
Missing	3 (3.2)	4	6.2	2 (2.6)	2	3.7
Depressed mood						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	10 (1.2)	10	0.9	7 (1.2)	7	0.9
Missing	2 (2.1)	3	4.7	2 (2.6)	2	3.7
Depression						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	11 (1.3)	12	1.1	14 (2.5)	15	2.0
Anhedonia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Major depression						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Tearfulness						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Negative thoughts						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Depressive symptom						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Persistent depressive disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Sleep disorders and disturbances						
>= 20% Weight loss	13 (3.4)	13	2.4	0		
< 20% Weight loss	26 (3.2)	28	2.6	27 (4.8)	31	4.1
Missing	1 (1.1)	1	1.6	2 (2.6)	2	3.7
Insomnia						
>= 20% Weight loss	11 (2.8)	11	2.0	0		
< 20% Weight loss	16 (1.9)	17	1.6	17 (3.0)	18	2.4
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Sleep disorder						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	6 (1.1)	7	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	0			1 (1.3)	1	1.9
Initial insomnia						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	4	0.4	1 (0.2)	1	0.1
Abnormal dreams						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Middle insomnia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Nightmare						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	3	0.4
Sleep terror						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Sexual dysfunctions, disturbances and gender identity disorders						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Libido increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Libido decreased						
>= 20% Weight loss	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Mood disorders and disturbances NEC						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	7 (0.8)	7	0.6	3 (0.5)	3	0.4
Irritability						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Affective disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Apathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Mood swings						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Suicidal and self-injurious behaviours NEC						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	5	0.7
Suicidal ideation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	4	0.5
Suicide attempt						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Adjustment disorders (incl subtypes)						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	4 (0.7)	4	0.5
Adjustment disorder with depressed mood						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Adjustment disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Grief reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Changes in physical activity						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	4	0.4	0		
Restlessness						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Tic						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cognitive and attention disorders and disturbances						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Mental fatigue						
>= 20% Weight loss	1 (0.3)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	0				0			
Attention deficit/hyperactivity disorder								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Deliria (incl confusion)								
>= 20% Weight loss	1	(0.3)	2	0.4	0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Disorientation								
>= 20% Weight loss	1	(0.3)	2	0.4	0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Manic and bipolar mood disorders and disturbances								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Bipolar disorder								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Psychiatric and behavioural symptoms NEC								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	2	(0.4)	2	0.3
Abulia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Psychiatric symptom								
>= 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			2 (0.4)	2	0.3
Psychiatric disorders NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Alcoholic hangover						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Somatic symptom and related disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Conversion disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Reproductive system and breast disorders						
>= 20% Weight loss	38 (9.8)	46	8.4	0		
< 20% Weight loss	53 (6.4)	71	6.5	29 (5.1)	35	4.6
Missing	5 (5.3)	5	7.8	3 (3.8)	4	7.4
Menstrual cycle and uterine bleeding disorders						
>= 20% Weight loss	14 (3.6)	16	2.9	0		
< 20% Weight loss	28 (3.4)	34	3.1	7 (1.2)	10	1.3
Missing	3 (3.2)	3	4.7	0		
Menstruation irregular						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	8 (1.0)	8	0.7	0		
Missing	1 (1.1)	1	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Menorrhagia						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	6 (0.7)	8	0.7	3 (0.5)	3	0.4
Missing	1 (1.1)	1	1.6	0		
Metrorrhagia						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Dysmenorrhoea						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	6 (0.7)	7	0.6	1 (0.2)	3	0.4
Menstrual disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	5 (0.6)	5	0.5	0		
Dysfunctional uterine bleeding						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Amenorrhoea						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Oligomenorrhoea						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Menstruation delayed						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Premenstrual syndrome						

Adverse events with onset prior to randomisation are not included.
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Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Premenstrual pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Breast disorders						
>= 20% Weight loss	10	(2.6)	11 2.0	0		
< 20% Weight loss	7	(0.8)	9 0.8	6	(1.1)	6 0.8
Missing	0			1	(1.3)	2 3.7
Breast mass						
>= 20% Weight loss	4	(1.0)	4 0.7	0		
< 20% Weight loss	4	(0.5)	4 0.4	0		
Missing	0			1	(1.3)	2 3.7
Breast cyst						
>= 20% Weight loss	2	(0.5)	2 0.4	0		
< 20% Weight loss	2	(0.2)	2 0.2	1	(0.2)	1 0.1
Fibrocystic breast disease						
>= 20% Weight loss	2	(0.5)	2 0.4	0		
< 20% Weight loss	0			2	(0.4)	2 0.3
Breast disorder						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Breast inflammation						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	0			0		
Nipple pain						
>= 20% Weight loss	1	(0.3)	1 0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0		
Breast pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Breast fibrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Breast haematoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Vulvovaginal disorders (excl infections and inflammations)						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	3 (0.4)	3	0.3	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Vaginal haemorrhage						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	0		
Vulvovaginal discomfort						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Vulvovaginal dryness						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Vulvovaginal pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0		
Vaginal polyp						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Vulvovaginal pruritus						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Ovarian and fallopian tube disorders						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	5 (0.6)	5	0.5	3 (0.5)	3	0.4
Missing	1 (1.1)	1	1.6	0		
Ovarian cyst						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	2 (0.4)	2	0.3
Polycystic ovaries						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Hydrosalpinx						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Uterine, pelvic and broad ligament disorders						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	7 (0.8)	7	0.6	2 (0.4)	2	0.3
Uterine polyp						
>= 20% Weight loss	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			0		
Adenomyosis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Endometriosis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	1 <0.1	1	(0.2)	1 0.1
Uterine haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	3	(0.4)	3 0.3	1	(0.2)	1 0.1
Uterine enlargement						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Vaginal prolapse						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Menopause related conditions						
>= 20% Weight loss	2	(0.5)	2 0.4	0		
< 20% Weight loss	7	(0.8)	7 0.6	3	(0.5)	4 0.5
Missing	0			1	(1.3)	1 1.9
Atrophic vulvovaginitis						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	3	(0.4)	3 0.3	1	(0.2)	1 0.1
Missing	0			1	(1.3)	1 1.9
Menopausal symptoms						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	3	(0.4)	3 0.3	1	(0.2)	1 0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Postmenopausal haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	2	0.3
Reproductive tract disorders NEC						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Pelvic pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Genital rash						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Genital pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9
Testicular and epididymal disorders						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Testicular mass						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Testicular pain						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Testicular disorder						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Cervix disorders (excl infections and inflammations)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Cervical dysplasia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Cervical leukoplakia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Uterine cervical erosion						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Sexual function and fertility disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Dyspareunia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Erectile dysfunction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Female reproductive tract infections and inflammations						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Uterine inflammation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Prostatic disorders (excl infections and inflammations)						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Benign prostatic hyperplasia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Penile and scrotal disorders (excl infections and inflammations)						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Scrotal pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Vascular disorders						
>= 20% Weight loss	26 (6.7)	30	5.5	2 (20.0)	2	14.1
< 20% Weight loss	58 (7.0)	61	5.6	39 (6.9)	43	5.6
Missing	6 (6.4)	6	9.3	4 (5.1)	5	9.3
Vascular hypertensive disorders						
>= 20% Weight loss	8 (2.1)	8	1.5	0		
< 20% Weight loss	30 (3.6)	30	2.7	27 (4.8)	30	3.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	4 (4.3)	4	6.2	1 (1.3)	2	3.7
Hypertension						
>= 20% Weight loss	8 (2.1)	8	1.5	0		
< 20% Weight loss	29 (3.5)	29	2.7	26 (4.6)	29	3.8
Missing	3 (3.2)	3	4.7	1 (1.3)	2	3.7
Hypertensive emergency						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Essential hypertension						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hypertensive crisis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Decreased and nonspecific blood pressure disorders and shock						
>= 20% Weight loss	10 (2.6)	12	2.2	0		
< 20% Weight loss	7 (0.8)	7	0.6	2 (0.4)	2	0.3
Missing	2 (2.1)	2	3.1	0		
Hypotension						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	4 (0.5)	4	0.4	2 (0.4)	2	0.3
Missing	2 (2.1)	2	3.1	0		
Orthostatic hypotension						
>= 20% Weight loss	5 (1.3)	6	1.1	0		
< 20% Weight loss	3 (0.4)	3	0.3	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Circulatory collapse						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Vascular disorders NEC						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	7 (0.8)	8	0.7	3 (0.5)	3	0.4
Hot flush						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	6 (0.7)	6	0.5	2 (0.4)	2	0.3
Flushing						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Vascular haemorrhagic disorders						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	2 (0.2)	2	0.2	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Haematoma						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	2 (0.2)	2	0.2	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Arteriosclerosis, stenosis, vascular insufficiency and necrosis						
>= 20% Weight loss	3 (0.8)	3	0.5	1 (10.0)	1	7.1
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1
Missing	0			2 (2.6)	2	3.7
Peripheral venous disease						
>= 20% Weight loss	3 (0.8)	3	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			1	(0.2)	1 0.1
Peripheral coldness						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	0		
Aortic arteriosclerosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Arteriosclerosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Raynaud's phenomenon						
>= 20% Weight loss	0			1	(10.0)	1 7.1
< 20% Weight loss	0			0		
Missing	0			2	(2.6)	2 3.7
Venous varices						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	5	(0.6)	5 0.5	0		
Varicose vein						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	5	(0.6)	5 0.5	0		
Embolism and thrombosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	3	(0.4)	3 0.3	3	(0.5)	3 0.4
Thrombosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	1	(0.2)	1 0.1
Thrombophlebitis						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Deep vein thrombosis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Thrombophlebitis superficial								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Vascular infections and inflammations								
>= 20% Weight loss	0				0			
< 20% Weight loss	2	(0.2)	2	0.2	0			
Arteritis								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Phlebitis								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Lymphatic vessel disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Lymphoedema								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Investigations								
>= 20% Weight loss	24	(6.2)	27	4.9	3	(30.0)	3	21.2
< 20% Weight loss	66	(8.0)	88	8.1	42	(7.4)	60	7.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	3 (3.2)	3	4.7	4 (5.1)	4	7.4
Hepatobiliary investigations						
>= 20% Weight loss	5 (1.3)	6	1.1	2 (20.0)	2	14.1
< 20% Weight loss	11 (1.3)	11	1.0	9 (1.6)	13	1.7
Gamma-glutamyltransferase increased						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	3 (0.5)	3	0.4
Hepatic enzyme increased						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	5 (0.6)	5	0.5	1 (0.2)	1	0.1
Alanine aminotransferase increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			3 (0.5)	3	0.4
Aspartate aminotransferase increased						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	0			3 (0.5)	3	0.4
Blood bilirubin increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Transaminases increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Lipid analyses						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	4 (0.5)	11	1.0	3 (0.5)	4	0.5
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Lipids increased						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
High density lipoprotein decreased						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Blood cholesterol increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Low density lipoprotein increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Blood triglycerides increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Very low density lipoprotein increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal investigations						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	9 (1.1)	11	1.0	2 (0.4)	2	0.3
Lipase increased						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	9 (1.1)	9	0.8	2 (0.4)	2	0.3
Gastric pH						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Pancreatic enzymes increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Amylase increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Protein and chemistry analyses NEC						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	11 (1.3)	11	1.0	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
C-reactive protein increased						
>= 20% Weight loss	2 (0.5)	2	0.4	1 (10.0)	1	7.1
< 20% Weight loss	11 (1.3)	11	1.0	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Renal and urinary tract investigations and urinalyses						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Blood creatinine increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Glomerular filtration rate decreased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
White blood cells urine						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Blood urine present						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Cardiac and vascular investigations (excl enzyme tests)						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	9 (1.1)	10	0.9	6 (1.1)	6	0.8
Missing	0			1 (1.3)	1	1.9
Blood pressure decreased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Blood pressure increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			6 (1.1)	6	0.8
Heart rate increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
QRS axis abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Blood pressure abnormal						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cardiac murmur						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Electrocardiogram ST segment depression						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave amplitude decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave inversion						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pulse abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Electrocardiogram T wave abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9
Physical examination and organ system status topics						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	4	0.5
Weight decreased						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Body mass index decreased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Weight increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Respiratory rate increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Body temperature increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	2	0.3
Cytogenetic investigations						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Prostatic specific antigen increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Endocrine investigations (incl sex hormones)						
>= 20% Weight loss	0			0		
< 20% Weight loss	8 (1.0)	10	0.9	3 (0.5)	3	0.4
Blood calcitonin increased						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	1	0.1
Blood thyroid stimulating hormone decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Blood thyroid stimulating hormone abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Thyroxine free increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Thyroxine increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Blood thyroid stimulating hormone increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Enzyme investigations NEC						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	5	0.5	8 (1.4)	8	1.1
Blood creatine phosphokinase increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	7 (1.2)	7	0.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Enzyme level increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Blood alkaline phosphatase increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Microbiology and serology investigations						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Helicobacter test positive						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Human papilloma virus test positive						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
HIV test positive						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Reproductive organ and breast investigations (excl hormone analyses)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Biopsy breast						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Haematology investigations (incl blood groups)						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	2 (0.4)	5	0.7
Haemoglobin decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Haematology test abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Haematocrit increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Haemoglobin increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Red blood cell count increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Red cell distribution width increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Investigations, imaging and histopathology procedures NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
Precancerous cells present						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Smear test						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Endoscopy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Metabolic, nutritional and blood gas investigations						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	4	(0.7)	4 0.5
Blood glucose increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	2	(0.4)	2 0.3
Blood uric acid increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Glycosylated haemoglobin increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Vitamin D decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Water, electrolyte and mineral investigations						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	3 (0.5)	3	0.4
Blood calcium decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Blood potassium increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Blood iron decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Blood sodium increased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Serum ferritin decreased						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Musculoskeletal and soft tissue investigations (excl enzyme tests)						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Arthroscopy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Immunology and allergy investigations						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Antinuclear antibody positive						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Cardiac disorders						
>= 20% Weight loss	13 (3.4)	15	2.7	1 (10.0)	1	7.1
< 20% Weight loss	37 (4.5)	43	3.9	31 (5.5)	42	5.5
Missing	4 (4.3)	4	6.2	1 (1.3)	1	1.9
Cardiac arrhythmias						
>= 20% Weight loss	10 (2.6)	10	1.8	1 (10.0)	1	7.1
< 20% Weight loss	21 (2.5)	27	2.5	16 (2.8)	20	2.6
Missing	1 (1.1)	1	1.6	0		
Tachycardia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	5 (0.9)	5	0.7
Missing	1 (1.1)	1	1.6	0		
Atrial fibrillation						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	7	0.6	3 (0.5)	4	0.5
Atrioventricular block first degree						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	4 (0.7)	4	0.5
Sinus tachycardia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Arrhythmia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Bradycardia						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	0			2 (0.4)	2	0.3
Cardiac flutter						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Nodal rhythm						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Bundle branch block left						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Ventricular extrasystoles						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Atrial flutter						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Atrial tachycardia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Atrioventricular block						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Atrioventricular block second degree						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Bundle branch block right						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Defect conduction intraventricular						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Sinus bradycardia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Supraventricular extrasystoles						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cardiac disorders, signs and symptoms NEC						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	6 (0.7)	6	0.5	8 (1.4)	10	1.3
Missing	3 (3.2)	3	4.7	0		
Palpitations						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	5	0.5	6 (1.1)	8	1.1
Missing	3 (3.2)	3	4.7	0		
Cardiovascular disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Hypertensive heart disease						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Coronary artery disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	6 (0.7)	6	0.5	6 (1.1)	7	0.9
Missing	0			1 (1.3)	1	1.9
Acute myocardial infarction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Angina pectoris						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Angina unstable						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Arteriosclerosis coronary artery						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Coronary artery stenosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Coronary artery disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Myocardial infarction						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			2 (0.4)	2	0.3

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cardiac neoplasms						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Pericardial cyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Cardiac valve disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	2	0.3
Aortic valve incompetence						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Aortic valve sclerosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Mitral valve incompetence						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Tricuspid valve incompetence						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Myocardial disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	3 (0.5)	3	0.4
Left ventricular hypertrophy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Cardiomegaly								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Cardiomyopathy								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Myocarditis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Pericardial disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Pericardial disease								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Eye disorders								
>= 20% Weight loss	13	(3.4)	23	4.2	1	(10.0)	1	7.1
< 20% Weight loss	29	(3.5)	33	3.0	20	(3.5)	27	3.5
Missing	2	(2.1)	2	3.1	3	(3.8)	3	5.6
Vision disorders								
>= 20% Weight loss	5	(1.3)	7	1.3	1	(10.0)	1	7.1
< 20% Weight loss	8	(1.0)	9	0.8	3	(0.5)	3	0.4
Missing	1	(1.1)	1	1.6	0			
Vision blurred								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	4	(0.5)	4	0.4	1	(0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Myopia						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Diplopia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	3	0.3	0		
Anisometropia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Astigmatism						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Photopsia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Visual impairment						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Scintillating scotoma						
>= 20% Weight loss	0			1 (10.0)	1	7.1
< 20% Weight loss	0			0		
Ocular structural change, deposit and degeneration NEC						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Macular degeneration						
>= 20% Weight loss	2 (0.5)	3	0.5	0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Vitreous detachment						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Eye disorders NEC						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	5 (0.6)	5	0.5	5 (0.9)	5	0.7
Missing	0			1 (1.3)	1	1.9
Dry eye						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Eyelid disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Lacrimation increased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Eye pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Ocular discomfort						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Ocular infections, irritations and inflammations						
>= 20% Weight loss	3 (0.8)	5	0.9	0		
< 20% Weight loss	5 (0.6)	5	0.5	7 (1.2)	10	1.3
Eye pruritus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Conjunctivitis allergic						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Eczema eyelids						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Meibomian gland dysfunction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Swelling of eyelid						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Conjunctival irritation						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Eye allergy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Eye discharge						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ocular hyperaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Blepharitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Conjunctival hyperaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Erythema of eyelid						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Eye inflammation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	2	0.3
Eye irritation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Keratitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Ulcerative keratitis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Anterior eye structural change, deposit and degeneration						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	5 (0.6)	6	0.5	2 (0.4)	3	0.4
Missing	0			1 (1.3)	1	1.9
Cataract						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	5	0.5	1 (0.2)	2	0.3
Xerophthalmia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ectropion						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9
Pterygium						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Glaucoma and ocular hypertension						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	2	0.3
Glaucoma						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	2	0.3
Retina, choroid and vitreous haemorrhages and vascular disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Retinopathy						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Retinal aneurysm						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Ocular haemorrhages and vascular disorders NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Optic ischaemic neuropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Eyelid haematoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Conjunctival haemorrhage						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Ocular neuromuscular disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Blepharospasm						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Ocular sensory symptoms NEC						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Asthenopia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ear and labyrinth disorders						
>= 20% Weight loss	18 (4.6)	22	4.0	0		
< 20% Weight loss	26 (3.2)	33	3.0	22 (3.9)	27	3.5
Missing	1 (1.1)	1	1.6	2 (2.6)	2	3.7
Inner ear and VIIIth cranial nerve disorders						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	14 (1.7)	18	1.6	17 (3.0)	21	2.8
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Vertigo						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	11 (1.3)	11	1.0	11 (1.9)	12	1.6
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Tinnitus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	3	0.3	2 (0.4)	3	0.4
Vertigo positional						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	4	0.4	3 (0.5)	4	0.5
Meniere's disease						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0		
Motion sickness						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	2	0.3
Aural disorders NEC						
>= 20% Weight loss	7 (1.8)	8	1.5	0		
< 20% Weight loss	8 (1.0)	8	0.7	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Ear pain						
>= 20% Weight loss	7 (1.8)	8	1.5	0		
< 20% Weight loss	5 (0.6)	5	0.5	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Ear discomfort						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Ear congestion						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Middle ear disorders (excl congenital)						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	2 (0.2)	3	0.3	2 (0.4)	2	0.3
Eustachian tube dysfunction						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	3	0.3	1 (0.2)	1	0.1
Eustachian tube disorder						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Tympanic membrane disorder						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hearing disorders						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	2 (0.4)	2	0.3
Deafness neurosensory						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Sudden hearing loss						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Hypoacusis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Deafness						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hyperacusis						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
External ear disorders (excl congenital)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Cerumen impaction						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	2	(0.2)	2	0.2	0			
Excessive cerumen production								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
>= 20% Weight loss	10	(2.6)	10	1.8	0			
< 20% Weight loss	34	(4.1)	40	3.7	21	(3.7)	23	3.0
Missing	2	(2.1)	2	3.1	4	(5.1)	4	7.4
Miscellaneous and site unspecified neoplasms malignant and unspecified								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Missing	1	(1.1)	1	1.6	0			
Neoplasm								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				0			
Missing	1	(1.1)	1	1.6	0			
Squamous cell carcinoma								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Cutaneous neoplasms benign								
>= 20% Weight loss	0				0			
< 20% Weight loss	10	(1.2)	14	1.3	6	(1.1)	6	0.8
Melanocytic naevus								
>= 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	7 (0.8)	8	0.7	2 (0.4)	2	0.3
Acrochordon						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Seborrhoeic keratosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Dysplastic naevus						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin papilloma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Pyogenic granuloma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Reproductive neoplasms male malignant and unspecified						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Prostate cancer						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Soft tissue neoplasms benign						
>= 20% Weight loss	2 (0.5)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Lipoma						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Leiomyoma						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Reproductive neoplasms female benign						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	5 (0.6)	5	0.5	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Uterine leiomyoma						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	4 (0.5)	4	0.4	3 (0.5)	3	0.4
Missing	0			1 (1.3)	1	1.9
Ovarian adenoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Skin neoplasms malignant and unspecified						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	3 (0.5)	3	0.4
Basal cell carcinoma						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Malignant melanoma						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Malignant melanoma in situ						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Neoplasm skin						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Breast neoplasms malignant and unspecified (incl nipple)						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	3 (0.5)	3	0.4
Breast cancer						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Intraductal proliferative breast lesion						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Invasive ductal breast carcinoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Lobular breast carcinoma in situ						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Phyllodes tumour						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Endocrine neoplasms benign						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Benign neoplasm of thyroid gland						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Parathyroid tumour benign						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hepatic and biliary neoplasms benign						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Haemangioma of liver						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal neoplasms benign						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Colon adenoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Reproductive neoplasms female malignant and unspecified						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Cervix carcinoma stage 0						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Breast neoplasms benign (incl nipple)						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Benign breast neoplasm						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Missing	0			1 (1.3)	1	1.9
Endocrine neoplasms malignant and unspecified						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Papillary thyroid cancer						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal neoplasms malignant and unspecified						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gastrointestinal stromal tumour						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hepatobiliary neoplasms malignant and unspecified						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Hepatic neoplasm								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Miscellaneous and site unspecified neoplasms benign								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Fibroma								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Adenoma benign								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Skeletal neoplasms benign								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Haemangioma of bone								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Soft tissue neoplasms malignant and unspecified								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Dermatofibrosarcoma protuberans								
>= 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Leukaemias						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Hairy cell leukaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Nervous system neoplasms malignant and unspecified NEC						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1	(1.3)	1 1.9
Glioblastoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1	(1.3)	1 1.9
Ocular neoplasms						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Eyelid haemangioma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Plasma cell neoplasms						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1	(0.2)	1 0.1
Paraproteinaemia						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.2)	1	0.1
Renal and urinary tract neoplasms benign						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Kidney angiomyolipoma						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Renal and urinary tract neoplasms malignant and unspecified						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Urinary tract neoplasm						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hepatobiliary disorders						
>= 20% Weight loss	16 (4.1)	21	3.8	0		
< 20% Weight loss	27 (3.3)	33	3.0	12 (2.1)	13	1.7
Missing	1 (1.1)	2	3.1	1 (1.3)	1	1.9
Gallbladder disorders						
>= 20% Weight loss	12 (3.1)	16	2.9	0		
< 20% Weight loss	18 (2.2)	20	1.8	4 (0.7)	4	0.5
Missing	1 (1.1)	2	3.1	1 (1.3)	1	1.9
Cholelithiasis						
>= 20% Weight loss	10 (2.6)	10	1.8	0		
< 20% Weight loss	12 (1.5)	12	1.1	4 (0.7)	4	0.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	2	3.1	0		
Cholecystitis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Missing	0			1 (1.3)	1	1.9
Cholecystitis acute						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Cholecystitis chronic						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Gallbladder disorder						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Biliary dyskinesia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hepatic and hepatobiliary disorders						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	10 (1.2)	13	1.2	9 (1.6)	9	1.2
Hepatic steatosis						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	4	0.4	7 (1.2)	7	0.9
Hepatic function abnormal						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hepatic cyst						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0			
< 20% Weight loss	2	(0.2)	2	0.2	1	(0.2)	1	0.1
Granulomatous liver disease								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Hepatic pain								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Hypertransaminasaemia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	3	0.3	0			
Nonalcoholic fatty liver disease								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Portal vein thrombosis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Bile duct disorders								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	0				0			
Bile duct stone								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			
Biliary colic								
>= 20% Weight loss	1	(0.3)	1	0.2	0			
< 20% Weight loss	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Renal and urinary disorders						
>= 20% Weight loss	10 (2.6)	10	1.8	1 (10.0)	1	7.1
< 20% Weight loss	29 (3.5)	38	3.5	17 (3.0)	19	2.5
Missing	2 (2.1)	3	4.7	4 (5.1)	4	7.4
Urinary tract signs and symptoms						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	18 (2.2)	21	1.9	5 (0.9)	6	0.8
Missing	1 (1.1)	1	1.6	3 (3.8)	3	5.6
Dysuria						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	7 (0.8)	9	0.8	0		
Renal pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Haematuria						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Chromaturia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pollakiuria						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Stress urinary incontinence						
>= 20% Weight loss	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Urine flow decreased						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Bladder pain						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Micturition urgency						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	0			1 (1.3)	1	1.9
Nocturia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Renal colic						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	2	0.2	0		
Urine odour abnormal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Polyuria						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Urinary incontinence						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	0			1 (1.3)	1	1.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Urinary retention						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Renal disorders (excl nephropathies)						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	4 (0.5)	5	0.5	7 (1.2)	8	1.1
Missing	1 (1.1)	2	3.1	0		
Acute kidney injury						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Renal impairment						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Renal cyst						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	4 (0.7)	4	0.5
Chronic kidney disease						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Hydronephrosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Nephrectasia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hypertensive nephropathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Urolithiases						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	10 (1.2)	11	1.0	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Nephrolithiasis						
>= 20% Weight loss	1 (0.3)	1	0.2	1 (10.0)	1	7.1
< 20% Weight loss	7 (0.8)	7	0.6	4 (0.7)	4	0.5
Missing	0			1 (1.3)	1	1.9
Calculus urinary						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Ureterolithiasis						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Bladder and bladder neck disorders (excl calculi)						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Cystitis noninfective						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Urethral disorders (excl calculi)						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Urethritis noninfective						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Blood and lymphatic system disorders						
>= 20% Weight loss	7 (1.8)	7	1.3	0		
< 20% Weight loss	27 (3.3)	29	2.7	15 (2.6)	20	2.6
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Anaemias nonhaemolytic and marrow depression						
>= 20% Weight loss	6 (1.5)	6	1.1	0		
< 20% Weight loss	17 (2.1)	18	1.6	9 (1.6)	10	1.3
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Anaemia						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	13 (1.6)	14	1.3	8 (1.4)	9	1.2
Missing	1 (1.1)	1	1.6	1 (1.3)	1	1.9
Blood loss anaemia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Iron deficiency anaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Hypochromic anaemia						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pernicious anaemia						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Pancytopenia						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Spleen, lymphatic and reticuloendothelial system disorders						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	6 (0.7)	6	0.5	3 (0.5)	4	0.5
Lymphadenopathy						
>= 20% Weight loss	0			0		
< 20% Weight loss	4 (0.5)	4	0.4	1 (0.2)	2	0.3
Splenic haemorrhage						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Hypersplenism						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Splenomegaly						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
White blood cell disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Leukocytosis						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Eosinophilia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Platelet disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	4	(0.7)	4	0.5
Thrombocytopenia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	4	(0.7)	4	0.5
Red blood cell disorders								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1
Polycythaemia								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			
Microcytosis								
>= 20% Weight loss	0				0			
< 20% Weight loss	0				1	(0.2)	1	0.1
Surgical and medical procedures								
>= 20% Weight loss	10	(2.6)	10	1.8	0			
< 20% Weight loss	6	(0.7)	7	0.6	8	(1.4)	8	1.1
Missing	2	(2.1)	2	3.1	0			
Therapeutic procedures and supportive care NEC								
>= 20% Weight loss	2	(0.5)	2	0.4	0			
< 20% Weight loss	1	(0.1)	1	<0.1	1	(0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Missing	1 (1.1)	1	1.6	0		
Cyst removal						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Polypectomy						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Spinal anaesthesia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Skin and subcutaneous tissue therapeutic procedures						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Acrochordon excision						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Skin neoplasm excision						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Head and neck therapeutic procedures						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	3 (0.4)	3	0.3	1 (0.2)	1	0.1
Dental operation						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Dental implantation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Sinus operation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Tooth extraction						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Gastrointestinal therapeutic procedures						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			2 (0.4)	2	0.3
Gastric bypass						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Abdominoplasty						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hepatobiliary therapeutic procedures						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Cholecystectomy						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Nervous system, skull and spine therapeutic procedures						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Intervertebral disc operation						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Soft tissue therapeutic procedures						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Lipoma excision						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Bone and joint therapeutic procedures						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	2 (0.4)	2	0.3
Synovial cyst removal						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Bone prosthesis insertion						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hip surgery						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Eye therapeutic procedures						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Glaucoma surgery						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Obstetric and gynaecological therapeutic procedures						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Abortion induced						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Ovarian operation						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Immune system disorders						
>= 20% Weight loss	9 (2.3)	9	1.6	0		
< 20% Weight loss	19 (2.3)	19	1.7	20 (3.5)	21	2.8
Missing	0			1 (1.3)	2	3.7
Allergic conditions						
>= 20% Weight loss	9 (2.3)	9	1.6	0		
< 20% Weight loss	18 (2.2)	18	1.6	20 (3.5)	21	2.8
Missing	0			1 (1.3)	2	3.7
Seasonal allergy						
>= 20% Weight loss	5 (1.3)	5	0.9	0		
< 20% Weight loss	10 (1.2)	10	0.9	13 (2.3)	13	1.7
Missing	0			1 (1.3)	1	1.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Hypersensitivity						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	5 (0.9)	5	0.7
Missing	0			1 (1.3)	1	1.9
Allergy to arthropod bite						
>= 20% Weight loss	0			0		
< 20% Weight loss	3 (0.4)	3	0.3	0		
Allergy to arthropod sting						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Rubber sensitivity						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Drug hypersensitivity						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Food allergy						
>= 20% Weight loss	0			0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Mite allergy						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Multiple allergies						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Immune disorders NEC						
>= 20% Weight loss	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Immunisation reaction						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Endocrine disorders						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	9 (1.1)	10	0.9	6 (1.1)	7	0.9
Missing	1 (1.1)	1	1.6	0		
Thyroid gland disorders						
>= 20% Weight loss	4 (1.0)	5	0.9	0		
< 20% Weight loss	8 (1.0)	9	0.8	6 (1.1)	6	0.8
Missing	1 (1.1)	1	1.6	0		
Goitre						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Missing	1 (1.1)	1	1.6	0		
Hypothyroidism						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	3 (0.4)	3	0.3	4 (0.7)	4	0.5
Hyperthyroidism						
>= 20% Weight loss	1 (0.3)	2	0.4	0		
< 20% Weight loss	2 (0.2)	2	0.2	0		
Thyroid mass						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	2 (0.2)	2	0.2	1 (0.2)	1	0.1
Thyroid cyst						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Primary hyperthyroidism						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Adrenal gland disorders						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Hyperadrenocorticism						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Endocrine disorders of gonadal function						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Hypogonadism						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Social circumstances						
>= 20% Weight loss	4 (1.0)	4	0.7	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1
Missing	1 (1.1)	1	1.6	0		
Lifestyle issues						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Bedridden						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			0		
Missing	1 (1.1)	1	1.6	0		
Age related factors						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Menopause						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			0		
Economic and housing issues						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Stress at work						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Family issues						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Family stress						
>= 20% Weight loss	0			0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Congenital, familial and genetic disorders						
>= 20% Weight loss	3 (0.8)	3	0.5	0		
< 20% Weight loss	1 (0.1)	1	<0.1	1 (0.2)	1	0.1

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R
Metabolic and nutritional disorders congenital						
>= 20% Weight loss	2 (0.5)	2	0.4	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Type V hyperlipidaemia						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	1 (0.1)	1	<0.1	0		
Gilbert's syndrome						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Musculoskeletal and connective tissue disorders congenital						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Carpus curvus						
>= 20% Weight loss	1 (0.3)	1	0.2	0		
< 20% Weight loss	0			0		
Skin and subcutaneous tissue disorders congenital						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Dermoid cyst						
>= 20% Weight loss	0			0		
< 20% Weight loss	0			1 (0.2)	1	0.1
Pregnancy, puerperium and perinatal conditions						

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	4	(0.5)	4 0.4	0		
Abortions and stillbirth						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	2	(0.2)	2 0.2	0		
Abortion spontaneous						
>= 20% Weight loss	1	(0.3)	1 0.2	0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Abortion						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Maternal complications of pregnancy						
>= 20% Weight loss	0			0		
< 20% Weight loss	2	(0.2)	2 0.2	0		
Ectopic pregnancy						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Morning sickness						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Product issues						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		
Device issues						
>= 20% Weight loss	0			0		
< 20% Weight loss	1	(0.1)	1 <0.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 1

	Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R
Device expulsion								
>= 20% Weight loss	0				0			
< 20% Weight loss	1	(0.1)	1	<0.1	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

53 Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
>= 20% Weight loss	19	26.6			51	72.6			6	7.9		
< 20% Weight loss	360	491.4			337	452.3			369	504.3		
Missing	23	11.8			15	8.2			27	16.1		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
>= 20% Weight loss	17	(89.5)	154	578.3	45	(88.2)	331	455.9	6	(100)	32	403.3
< 20% Weight loss	296	(82.2)	1643	334.4	296	(87.8)	1811	400.4	288	(78.0)	1285	254.8
Missing	16	(69.6)	62	526.3	12	(80.0)	55	672.5	15	(55.6)	71	442.0
Serious												
Yes												
>= 20% Weight loss	3	(15.8)	8	30.0	5	(9.8)	13	17.9	3	(50.0)	8	100.8
< 20% Weight loss	27	(7.5)	44	9.0	32	(9.5)	43	9.5	31	(8.4)	40	7.9
Missing	1	(4.3)	1	8.5	3	(20.0)	15	183.4	3	(11.1)	5	31.1
No												
>= 20% Weight loss	17	(89.5)	146	548.2	45	(88.2)	318	438.0	6	(100)	24	302.5
< 20% Weight loss	293	(81.4)	1599	325.4	296	(87.8)	1768	390.9	286	(77.5)	1245	246.9
Missing	16	(69.6)	61	517.8	11	(73.3)	40	489.1	15	(55.6)	66	410.9
Severity												
Severe												
>= 20% Weight loss	1	(5.3)	7	26.3	5	(9.8)	11	15.2	1	(16.7)	2	25.2
< 20% Weight loss	21	(5.8)	36	7.3	19	(5.6)	25	5.5	22	(6.0)	29	5.8
Missing	0				3	(20.0)	15	183.4	5	(18.5)	8	49.8
Moderate												
>= 20% Weight loss	10	(52.6)	18	67.6	24	(47.1)	89	122.6	4	(66.7)	21	264.7

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severity												
Moderate												
< 20% Weight loss	117	(32.5)	268	54.5	142	(42.1)	401	88.7	107	(29.0)	219	43.4
Missing	8	(34.8)	29	246.2	7	(46.7)	18	220.1	7	(25.9)	24	149.4
Mild												
>= 20% Weight loss	16	(84.2)	129	484.4	40	(78.4)	231	318.2	4	(66.7)	9	113.4
< 20% Weight loss	277	(76.9)	1339	272.5	281	(83.4)	1385	306.2	265	(71.8)	1037	205.6
Missing	13	(56.5)	33	280.1	7	(46.7)	22	269.0	10	(37.0)	39	242.8
Relationship to trial product												
Missing												
>= 20% Weight loss	0				2	(3.9)	2	2.8	0			
< 20% Weight loss	10	(2.8)	11	2.2	8	(2.4)	8	1.8	5	(1.4)	5	1.0
Missing	0				0				1	(3.7)	2	12.5
Probable												
>= 20% Weight loss	5	(26.3)	11	41.3	22	(43.1)	69	95.0	3	(50.0)	5	63.0
< 20% Weight loss	118	(32.8)	300	61.1	143	(42.4)	374	82.7	57	(15.4)	93	18.4
Missing	10	(43.5)	33	280.1	4	(26.7)	13	159.0	2	(7.4)	2	12.5
Possible												
>= 20% Weight loss	8	(42.1)	52	195.3	26	(51.0)	76	104.7	1	(16.7)	1	12.6
< 20% Weight loss	142	(39.4)	347	70.6	150	(44.5)	441	97.5	87	(23.6)	152	30.1
Missing	3	(13.0)	8	67.9	6	(40.0)	17	207.9	5	(18.5)	17	105.8
Unlikely												
>= 20% Weight loss	17	(89.5)	91	341.7	40	(78.4)	184	253.4	6	(100)	26	327.7
< 20% Weight loss	266	(73.9)	985	200.5	253	(75.1)	988	218.5	268	(72.6)	1035	205.2
Missing	13	(56.5)	21	178.3	8	(53.3)	25	305.7	15	(55.6)	50	311.3
Outcome												
Fatal												
>= 20% Weight loss	0				0				0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Outcome												
Fatal												
< 20% Weight loss	0				0				0			
Missing	0				1	(6.7)	1	12.2	1	(3.7)	1	6.2
Recovered												
>= 20% Weight loss	16	(84.2)	110	413.1	42	(82.4)	282	388.4	6	(100)	27	340.3
< 20% Weight loss	283	(78.6)	1338	272.3	280	(83.1)	1483	327.9	266	(72.1)	977	193.7
Missing	16	(69.6)	55	466.9	11	(73.3)	47	574.7	13	(48.1)	50	311.3
Recovering												
>= 20% Weight loss	1	(5.3)	4	15.0	2	(3.9)	3	4.1	0			
< 20% Weight loss	17	(4.7)	27	5.5	14	(4.2)	22	4.9	17	(4.6)	19	3.8
Missing	1	(4.3)	1	8.5	1	(6.7)	1	12.2	0			
Recovered With Sequelae												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	5	(1.4)	5	1.0	4	(1.2)	4	0.9	1	(0.3)	1	0.2
Missing	0				1	(6.7)	1	12.2	0			
Not Recovered												
>= 20% Weight loss	12	(63.2)	40	150.2	22	(43.1)	46	63.4	2	(33.3)	5	63.0
< 20% Weight loss	132	(36.7)	273	55.6	140	(41.5)	298	65.9	148	(40.1)	286	56.7
Missing	3	(13.0)	6	50.9	1	(6.7)	1	12.2	6	(22.2)	19	118.3
Unknown												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				3	(0.9)	4	0.9	2	(0.5)	2	0.4
Missing	0				1	(6.7)	4	48.9	1	(3.7)	1	6.2
Leading to												
Permanent treatment discontinuation												
>= 20% Weight loss	1	(5.3)	1	3.8	0				0			
< 20% Weight loss	14	(3.9)	15	3.1	22	(6.5)	29	6.4	10	(2.7)	14	2.8
Missing	5	(21.7)	7	59.4	3	(20.0)	5	61.1	4	(14.8)	4	24.9

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Leading to												
Temporary interruption of trial product												
>= 20% Weight loss	2	(10.5)	2	7.5	3	(5.9)	8	11.0	1	(16.7)	1	12.6
< 20% Weight loss	18	(5.0)	35	7.1	32	(9.5)	64	14.2	13	(3.5)	18	3.6
Missing	6	(26.1)	10	84.9	2	(13.3)	18	220.1	1	(3.7)	1	6.2
Dose reduction of trial product												
>= 20% Weight loss	0				5	(9.8)	9	12.4	1	(16.7)	1	12.6
< 20% Weight loss	17	(4.7)	27	5.5	27	(8.0)	53	11.7	2	(0.5)	2	0.4
Missing	1	(4.3)	1	8.5	3	(20.0)	4	48.9	0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

54 Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
>= 20% Weight loss	19		26.6		51		72.6		6		7.9	
< 20% Weight loss	360		491.4		337		452.3		369		504.3	
Missing	23		11.8		15		8.2		27		16.1	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
>= 20% Weight loss	17	(89.5)	154	578.3	45	(88.2)	331	455.9	6	(100)	32	403.3
< 20% Weight loss	296	(82.2)	1643	334.4	296	(87.8)	1811	400.4	288	(78.0)	1285	254.8
Missing	16	(69.6)	62	526.3	12	(80.0)	55	672.5	15	(55.6)	71	442.0
Gastrointestinal disorders												
>= 20% Weight loss	11	(57.9)	61	229.1	37	(72.5)	142	195.6	3	(50.0)	6	75.6
< 20% Weight loss	208	(57.8)	624	127.0	211	(62.6)	754	166.7	124	(33.6)	239	47.4
Missing	12	(52.2)	39	331.0	8	(53.3)	28	342.4	11	(40.7)	17	105.8
Gastrointestinal signs and symptoms												
>= 20% Weight loss	11	(57.9)	44	165.2	31	(60.8)	118	162.5	2	(33.3)	2	25.2
< 20% Weight loss	165	(45.8)	365	74.3	164	(48.7)	465	102.8	67	(18.2)	102	20.2
Missing	11	(47.8)	23	195.2	5	(33.3)	18	220.1	7	(25.9)	11	68.5
Nausea												
>= 20% Weight loss	10	(52.6)	23	86.4	25	(49.0)	59	81.3	0			
< 20% Weight loss	111	(30.8)	165	33.6	106	(31.5)	182	40.2	33	(8.9)	41	8.1
Missing	8	(34.8)	10	84.9	5	(33.3)	8	97.8	4	(14.8)	4	24.9
Vomiting												
>= 20% Weight loss	3	(15.8)	12	45.1	14	(27.5)	39	53.7	0			
< 20% Weight loss	47	(13.1)	72	14.7	70	(20.8)	141	31.2	10	(2.7)	11	2.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	4 (17.4)	9	76.4	4 (26.7)	8	97.8	1 (3.7)	1	6.2
Dyspepsia									
>= 20% Weight loss	3 (15.8)	3	11.3	2 (3.9)	2	2.8	0		
< 20% Weight loss	23 (6.4)	23	4.7	22 (6.5)	27	6.0	5 (1.4)	5	1.0
Missing	1 (4.3)	1	8.5	1 (6.7)	1	12.2	0		
Abdominal pain upper									
>= 20% Weight loss	1 (5.3)	1	3.8	5 (9.8)	7	9.6	1 (16.7)	1	12.6
< 20% Weight loss	10 (2.8)	10	2.0	11 (3.3)	14	3.1	10 (2.7)	12	2.4
Abdominal distension									
>= 20% Weight loss	1 (5.3)	1	3.8	2 (3.9)	2	2.8	1 (16.7)	1	12.6
< 20% Weight loss	8 (2.2)	11	2.2	22 (6.5)	28	6.2	8 (2.2)	10	2.0
Missing	0			0			2 (7.4)	2	12.5
Eructation									
>= 20% Weight loss	1 (5.3)	1	3.8	3 (5.9)	3	4.1	0		
< 20% Weight loss	10 (2.8)	15	3.1	13 (3.9)	18	4.0	1 (0.3)	1	0.2
Abdominal pain									
>= 20% Weight loss	1 (5.3)	1	3.8	3 (5.9)	5	6.9	0		
< 20% Weight loss	16 (4.4)	19	3.9	10 (3.0)	10	2.2	4 (1.1)	4	0.8
Missing	0			0			1 (3.7)	1	6.2
Abdominal pain lower									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	2	0.4	3 (0.8)	3	0.6
Missing	0			1 (6.7)	1	12.2	0		
Flatulence									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	20 (5.6)	24	4.9	16 (4.7)	21	4.6	6 (1.6)	8	1.6
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Abdominal discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	13 (3.6)	15	3.1	13 (3.9)	15	3.3	5 (1.4)	5	1.0
Missing	2 (8.7)	2	17.0	0			2 (7.4)	2	12.5
Regurgitation									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Abnormal faeces									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Aerophagia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Epigastric discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal pain									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal sounds abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Abdominal rigidity									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Anal incontinence									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Breath odour									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Dysphagia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Faeces discoloured									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Faeces soft									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Retching									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastrointestinal motility and defaecation conditions									
>= 20% Weight loss	6 (31.6)	12	45.1	16 (31.4)	20	27.5	3 (50.0)	3	37.8
< 20% Weight loss	112 (31.1)	219	44.6	120 (35.6)	209	46.2	65 (17.6)	96	19.0
Missing	7 (30.4)	12	101.9	7 (46.7)	10	122.3	2 (7.4)	2	12.5
Diarrhoea									
>= 20% Weight loss	3 (15.8)	4	15.0	8 (15.7)	12	16.5	0		
< 20% Weight loss	81 (22.5)	145	29.5	73 (21.7)	121	26.8	47 (12.7)	65	12.9
Missing	5 (21.7)	9	76.4	5 (33.3)	8	97.8	1 (3.7)	1	6.2
Constipation									
>= 20% Weight loss	6 (31.6)	8	30.0	7 (13.7)	7	9.6	1 (16.7)	1	12.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	44 (12.2)	61	12.4	61 (18.1)	73	16.1	20 (5.4)	24	4.8
Missing	1 (4.3)	1	8.5	2 (13.3)	2	24.5	1 (3.7)	1	6.2
Gastrooesophageal reflux disease									
>= 20% Weight loss	0			0			2 (33.3)	2	25.2
< 20% Weight loss	11 (3.1)	12	2.4	12 (3.6)	13	2.9	5 (1.4)	5	1.0
Missing	2 (8.7)	2	17.0	0			0		
Irritable bowel syndrome									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Change of bowel habit									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Gastrointestinal motility disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal hypermotility									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gastrooesophageal sphincter insufficiency									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Dental and gingival conditions									
>= 20% Weight loss	0			3 (5.9)	3	4.1	0		
< 20% Weight loss	7 (1.9)	8	1.6	7 (2.1)	8	1.8	7 (1.9)	7	1.4
Missing	1 (4.3)	1	8.5	0			0		
Toothache									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	3 (0.8)	4	0.8	3 (0.9)	3	0.7	2 (0.5)	2	0.4
Missing	1 (4.3)	1	8.5	0			0		
Tooth deposit									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Dental caries									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	5 (1.4)	5	1.0
Gingival swelling									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Periodontal disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastrointestinal conditions NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	7 (1.9)	8	1.6	18 (5.3)	21	4.6	6 (1.6)	6	1.2
Hyperchlorhydria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	6	1.2	11 (3.3)	14	3.1	2 (0.5)	2	0.4
Food poisoning									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	0		
Gastrointestinal disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Barrett's oesophagus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Gastric disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gastrointestinal melanosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gastrointestinal inflammatory conditions									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	7 (1.9)	7	1.4	17 (5.0)	20	4.4	6 (1.6)	8	1.6
Missing	1 (4.3)	1	8.5	0			0		
Gastritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	5	1.0	11 (3.3)	13	2.9	4 (1.1)	6	1.2
Missing	1 (4.3)	1	8.5	0			0		
Enteritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	1 (0.3)	1	0.2
Enterocolitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Chronic gastritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Duodenitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Colitis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastrointestinal haemorrhages NEC									
>= 20% Weight loss	0			1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	1 (0.3)	1	0.2
Intra-abdominal haemorrhage									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Haematochezia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	0		
Mallory-Weiss syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Upper gastrointestinal haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Intra-abdominal haematoma									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Rectal haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal vascular conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	3	0.6	9 (2.7)	9	2.0	1 (0.3)	1	0.2
Missing	1 (4.3)	2	17.0	0			1 (3.7)	1	6.2
Haemorrhoids									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	3	0.6	9 (2.7)	9	2.0	1 (0.3)	1	0.2
Haemorrhoids thrombosed									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	1 (4.3)	1	8.5	0			0		
Varices oesophageal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2
Abdominal hernias and other abdominal wall conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	4 (1.2)	4	0.9	4 (1.1)	4	0.8
Missing	0			0			1 (3.7)	1	6.2
Abdominal hernia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Abdominal wall haematoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Hiatus hernia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Umbilical hernia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Inguinal hernia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Salivary gland conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	5	1.1	2 (0.5)	2	0.4
Dry mouth									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Parotid gland enlargement									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Salivary hypersecretion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Noninfective sialoadenitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Benign neoplasms gastrointestinal									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	4 (1.1)	4	0.8	3 (0.9)	3	0.7	3 (0.8)	3	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	0			0			1 (3.7)	1	6.2
Gastric polyps									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Large intestine polyp									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Missing	0			0			1 (3.7)	1	6.2
Oral soft tissue conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	4 (1.1)	4	0.8
Mouth ulceration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Stomatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Aphthous ulcer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Lip swelling									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Odynophagia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Anal and rectal conditions NEC									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Anal fissure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Diverticular disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	3 (0.8)	3	0.6
Diverticulum intestinal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Diverticulum									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			3 (0.8)	3	0.6
Exocrine pancreas conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Pancreatitis acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Obstructive pancreatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Pancreatic cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal stenosis and obstruction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Small intestinal obstruction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal ulceration and perforation									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Gastritis erosive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Diverticular perforation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Gastric ulcer									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Malabsorption conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Malabsorption									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Peritoneal and retroperitoneal conditions									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Retroperitoneal mass									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Tongue conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Glossodynia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Infections and infestations									
>= 20% Weight loss	8 (42.1)	19	71.3	28 (54.9)	57	78.5	4 (66.7)	9	113.4
< 20% Weight loss	154 (42.8)	294	59.8	149 (44.2)	285	63.0	163 (44.2)	329	65.2
Missing	4 (17.4)	5	42.4	2 (13.3)	3	36.7	8 (29.6)	21	130.7
Infections - pathogen unspecified									
>= 20% Weight loss	8 (42.1)	16	60.1	25 (49.0)	46	63.4	4 (66.7)	7	88.2
< 20% Weight loss	134 (37.2)	229	46.6	136 (40.4)	242	53.5	135 (36.6)	259	51.4
Missing	4 (17.4)	5	42.4	1 (6.7)	1	12.2	8 (29.6)	15	93.4
Nasopharyngitis									
>= 20% Weight loss	3 (15.8)	4	15.0	9 (17.6)	17	23.4	1 (16.7)	2	25.2
< 20% Weight loss	44 (12.2)	65	13.2	59 (17.5)	98	21.7	55 (14.9)	86	17.1
Missing	0			0			3 (11.1)	4	24.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Upper respiratory tract infection									
>= 20% Weight loss	3 (15.8)	4	15.0	4 (7.8)	6	8.3	0		
< 20% Weight loss	33 (9.2)	49	10.0	37 (11.0)	41	9.1	37 (10.0)	49	9.7
Missing	1 (4.3)	1	8.5	1 (6.7)	1	12.2	1 (3.7)	1	6.2
Gastroenteritis									
>= 20% Weight loss	0			4 (7.8)	4	5.5	0		
< 20% Weight loss	24 (6.7)	28	5.7	10 (3.0)	11	2.4	12 (3.3)	14	2.8
Missing	0			0			1 (3.7)	1	6.2
Sinusitis									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	6 (1.7)	6	1.2	12 (3.6)	17	3.8	10 (2.7)	11	2.2
Missing	0			0			1 (3.7)	2	12.5
Conjunctivitis									
>= 20% Weight loss	0			3 (5.9)	3	4.1	1 (16.7)	1	12.6
< 20% Weight loss	3 (0.8)	5	1.0	2 (0.6)	2	0.4	3 (0.8)	4	0.8
Bronchitis									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	9 (2.5)	10	2.0	13 (3.9)	15	3.3	13 (3.5)	15	3.0
Urinary tract infection									
>= 20% Weight loss	2 (10.5)	2	7.5	1 (2.0)	4	5.5	0		
< 20% Weight loss	14 (3.9)	18	3.7	12 (3.6)	12	2.7	12 (3.3)	16	3.2
Missing	1 (4.3)	1	8.5	0			0		
Cystitis									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	2 (0.5)	3	0.6
Missing	0			0			1 (3.7)	2	12.5
Paronychia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	3 (0.9)	3	0.7	2 (0.5)	2	0.4
Missing	1 (4.3)	1	8.5	0			0		
Pneumonia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	4	0.9	4 (1.1)	4	0.8
Missing	0			0			1 (3.7)	1	6.2
Tonsillitis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	3 (0.8)	3	0.6
Gastrointestinal infection									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	3	0.7	1 (0.3)	1	0.2
Localised infection									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Abscess									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Implant site infection									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Mastitis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Lower respiratory tract infection									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	6 (1.6)	6	1.2
Pharyngitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	7 (1.9)	7	1.4
Missing	1 (4.3)	1	8.5	0			0		
Acute sinusitis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	2	0.4	3 (0.8)	5	1.0
Otitis externa									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	4 (1.1)	4	0.8	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Tooth infection									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	3	0.6	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Appendicitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Breast abscess									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Chronic sinusitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Diverticulitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Missing	0			0			2 (7.4)	2	12.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Infected dermal cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Kidney infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Otitis media acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Periodontitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	2	0.4
Post procedural infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Respiratory tract infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	5 (1.4)	5	1.0
Missing	1 (4.3)	1	8.5	0			0		
Rhinitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	4 (1.1)	4	0.8
Skin infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	1 (0.3)	1	0.2
Tooth abscess									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	1 (0.3)	2	0.4
Urosepsis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Vulvovaginitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	2	0.4	0		
Colonic abscess									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Ear infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Missing	0			0			1 (3.7)	1	6.2
Empyema									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Eye infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Gingival abscess									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gingivitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Hordeolum												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				1	(0.3)	1	0.2
Joint abscess												
>= 20% Weight loss	0				0				1	(16.7)	1	12.6
< 20% Weight loss	0				0				0			
Labyrinthitis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			
Laryngitis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	3	(0.8)	4	0.8	0				0			
Mastoiditis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(0.3)	1	0.2
Osteomyelitis												
>= 20% Weight loss	0				0				1	(16.7)	1	12.6
< 20% Weight loss	0				0				0			
Otitis media												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(0.3)	1	0.2
Otitis media chronic												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(0.3)	1	0.2
Pericoronitis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Postoperative wound infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Pulpitis dental									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Pyelonephritis acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Sepsis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	0			0		
Sialoadenitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Sinobronchitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Subcutaneous abscess									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Tracheitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tracheobronchitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vaginal infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Wound infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Viral infectious disorders									
>= 20% Weight loss	3 (15.8)	3	11.3	5 (9.8)	7	9.6	0		
< 20% Weight loss	32 (8.9)	38	7.7	30 (8.9)	32	7.1	34 (9.2)	40	7.9
Missing	0			1 (6.7)	2	24.5	2 (7.4)	2	12.5
Viral infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	3 (0.8)	4	0.8
Missing	0			1 (6.7)	2	24.5	0		
Influenza									
>= 20% Weight loss	2 (10.5)	2	7.5	1 (2.0)	1	1.4	0		
< 20% Weight loss	15 (4.2)	17	3.5	14 (4.2)	15	3.3	17 (4.6)	21	4.2
Missing	0			0			1 (3.7)	1	6.2
Gastroenteritis viral									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	2	2.8	0		
< 20% Weight loss	4 (1.1)	4	0.8	5 (1.5)	5	1.1	6 (1.6)	6	1.2
Missing	0			0			1 (3.7)	1	6.2
Herpes zoster									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	2 (0.5)	2	0.4
Ophthalmic herpes zoster									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			0		
Respiratory tract infection viral									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	0			2 (0.5)	2	0.4
Viral diarrhoea									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Gastroenteritis norovirus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Herpes simplex									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Herpes virus infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Oral herpes									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	3	0.6	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Pneumonia influenzal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Viral pharyngitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Chikungunya virus infection									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Ear infection viral									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Rhinovirus infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Viral upper respiratory tract infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	4	0.8	0			1 (0.3)	1	0.2
Bacterial infectious disorders									
>= 20% Weight loss	0			3 (5.9)	3	4.1	1 (16.7)	2	25.2
< 20% Weight loss	10 (2.8)	13	2.6	5 (1.5)	5	1.1	10 (2.7)	14	2.8
Missing	0			0			1 (3.7)	2	12.5
Cellulitis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	5 (1.4)	6	1.2	1 (0.3)	1	0.2	3 (0.8)	4	0.8
Bacterial vaginosis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Pharyngitis streptococcal									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			2 (0.5)	2	0.4
Missing	0			0			1 (3.7)	2	12.5
Breast cellulitis									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ear infection bacterial									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	3	0.6	1 (0.3)	1	0.2	0		
Furuncle									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Staphylococcal infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	3	0.6
Clostridium difficile colitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Helicobacter gastritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Helicobacter infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Wound infection staphylococcal									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Fungal infectious disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	14 (3.9)	14	2.8	6 (1.8)	6	1.3	14 (3.8)	15	3.0
Missing	0			0			1 (3.7)	2	12.5
Vulvovaginal mycotic infection									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	0			3 (0.8)	3	0.6
Onychomycosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Fungal infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	0		
Fungal skin infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Tinea pedis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	3 (0.8)	3	0.6
Vulvovaginal candidiasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Missing	0			0			1 (3.7)	2	12.5
Balanitis candida									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Candida infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Dermatophytosis of nail									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Genital candidiasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Genital infection fungal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Skin candida									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Tinea infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			2 (0.5)	2	0.4
Tinea versicolour									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Ectoparasitic disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Acarodermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Nervous system disorders									
>= 20% Weight loss	3 (15.8)	11	41.3	14 (27.5)	20	27.5	3 (50.0)	6	75.6
< 20% Weight loss	58 (16.1)	92	18.7	67 (19.9)	96	21.2	57 (15.4)	80	15.9
Missing	2 (8.7)	2	17.0	1 (6.7)	2	24.5	3 (11.1)	6	37.4
Headaches									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	2 (10.5)	4	15.0	9 (17.6)	10	13.8	1 (16.7)	4	50.4
< 20% Weight loss	32 (8.9)	50	10.2	28 (8.3)	36	8.0	22 (6.0)	24	4.8
Missing	2 (8.7)	2	17.0	0			1 (3.7)	4	24.9
Headache									
>= 20% Weight loss	2 (10.5)	2	7.5	7 (13.7)	8	11.0	1 (16.7)	4	50.4
< 20% Weight loss	29 (8.1)	44	9.0	24 (7.1)	32	7.1	18 (4.9)	19	3.8
Missing	2 (8.7)	2	17.0	0			1 (3.7)	4	24.9
Migraine									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	0		
Migraine with aura									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Tension headache									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Occipital neuralgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Sinus headache									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Neurological disorders NEC									
>= 20% Weight loss	3 (15.8)	4	15.0	6 (11.8)	6	8.3	0		
< 20% Weight loss	25 (6.9)	29	5.9	30 (8.9)	40	8.8	29 (7.9)	36	7.1
Missing	0			0			2 (7.4)	2	12.5
Dizziness									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	2	7.5	5 (9.8)	5	6.9	0		
< 20% Weight loss	17 (4.7)	19	3.9	14 (4.2)	15	3.3	12 (3.3)	14	2.8
Missing	0			0			1 (3.7)	1	6.2
Paraesthesia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	6	1.3	6 (1.6)	7	1.4
Dysgeusia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			4 (1.2)	8	1.8	1 (0.3)	1	0.2
Hypoaesthesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	2 (0.5)	2	0.4
Dizziness postural									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	2 (0.6)	2	0.4	0		
Hyperaesthesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	0		
Somnolence									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	2 (0.5)	2	0.4
Syncope									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Ageusia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Aphasia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Coordination abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Dysaesthesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Head discomfort									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Hypogeusia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Lethargy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Loss of consciousness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Neuralgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Missing	0			0			1 (3.7)	1	6.2
Phantom limb syndrome									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Presyncope									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Restless legs syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Central nervous system vascular disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	2 (3.9)	3	4.1	0		
< 20% Weight loss	1 (0.3)	1	0.2	5 (1.5)	6	1.3	2 (0.5)	3	0.6
Missing	0			1 (6.7)	2	24.5	0		
Spinal epidural haematoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Subarachnoid haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Cerebrovascular accident									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Cerebral artery thrombosis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Carotid arteriosclerosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Carotid artery stenosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	0		
Cerebral artery stenosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cerebral infarction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ischaemic stroke									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			1 (0.3)	2	0.4
Peripheral neuropathies									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	5 (1.4)	6	1.2	3 (0.9)	3	0.7	7 (1.9)	8	1.6
Carpal tunnel syndrome									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	4	0.8	0			2 (0.5)	2	0.4
Diabetic neuropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Meralgia paraesthetica									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Neuropathy peripheral									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	3	0.6
Nerve compression									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Polyneuropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Spinal cord and nerve root disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	5	1.0	3 (0.9)	4	0.9	4 (1.1)	4	0.8
Sciatica									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Radiculopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Sacral radiculopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cervical radiculopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Cervicobrachial syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Lumbar radiculopathy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			2 (0.5)	2	0.4
Cranial nerve disorders (excl neoplasms)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Anosmia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Facial paralysis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Encephalopathies									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Hepatic encephalopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hyponatraemic encephalopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Mental impairment disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	4 (1.1)	4	0.8
Memory impairment									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Amnesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Dementia Alzheimer's type									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Vascular dementia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Sleep disturbances (incl subtypes)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hypersomnia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Structural brain disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cerebral ventricle dilatation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Movement disorders (incl parkinsonism)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tremor									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Neurological disorders of the eye									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Visual field defect									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Seizures (incl subtypes)									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Partial seizures									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Musculoskeletal and connective tissue disorders									
>= 20% Weight loss	5 (26.3)	8	30.0	13 (25.5)	18	24.8	0		
< 20% Weight loss	90 (25.0)	135	27.5	85 (25.2)	133	29.4	81 (22.0)	122	24.2
Missing	4 (17.4)	4	34.0	0			3 (11.1)	4	24.9
Musculoskeletal and connective tissue disorders NEC									
>= 20% Weight loss	2 (10.5)	2	7.5	8 (15.7)	9	12.4	0		
< 20% Weight loss	52 (14.4)	61	12.4	48 (14.2)	57	12.6	30 (8.1)	34	6.7
Missing	3 (13.0)	3	25.5	0			3 (11.1)	4	24.9
Back pain									
>= 20% Weight loss	1 (5.3)	1	3.8	4 (7.8)	4	5.5	0		
< 20% Weight loss	26 (7.2)	28	5.7	23 (6.8)	26	5.7	13 (3.5)	14	2.8
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Pain in extremity									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	11 (3.1)	11	2.2	15 (4.5)	15	3.3	8 (2.2)	8	1.6
Missing	1 (4.3)	1	8.5	0			2 (7.4)	2	12.5
Neck pain									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	1 (0.3)	1	0.2	6 (1.8)	6	1.3	3 (0.8)	3	0.6
Missing	1 (4.3)	1	8.5	0			0		
Musculoskeletal pain									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	8 (2.2)	8	1.6	6 (1.8)	6	1.3	6 (1.6)	6	1.2
Neck mass									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Flank pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	0		
Muscle contracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Musculoskeletal chest pain									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	4 (1.1)	5	1.0	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Rheumatic disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Axillary mass									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Limb mass									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	0			0		
Musculoskeletal discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Musculoskeletal stiffness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Plantar fasciitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Joint disorders									
>= 20% Weight loss	2 (10.5)	3	11.3	6 (11.8)	7	9.6	0		
< 20% Weight loss	36 (10.0)	43	8.8	38 (11.3)	50	11.1	41 (11.1)	49	9.7
Arthralgia									
>= 20% Weight loss	2 (10.5)	2	7.5	2 (3.9)	2	2.8	0		
< 20% Weight loss	22 (6.1)	25	5.1	21 (6.2)	27	6.0	20 (5.4)	20	4.0
Osteoarthritis									
>= 20% Weight loss	0			3 (5.9)	3	4.1	0		
< 20% Weight loss	2 (0.6)	2	0.4	8 (2.4)	11	2.4	12 (3.3)	13	2.6
Arthritis									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Spinal osteoarthritis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	6 (1.6)	6	1.2
Periarthritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	5	1.1	1 (0.3)	1	0.2
Rotator cuff syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	7	1.4	3 (0.9)	4	0.9	0		
Joint swelling									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Arthritis climacteric									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Arthropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Femoroacetabular impingement									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gouty arthritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Joint effusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Neuropathic arthropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Psoriatic arthropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Rheumatoid arthritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	2	0.4
Sacroiliitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tendon, ligament and cartilage disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	6 (1.7)	6	1.2	4 (1.2)	4	0.9	9 (2.4)	10	2.0
Trigger finger									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Osteochondrosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Tendon disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Tendonitis									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	6 (1.6)	6	1.2
Costochondritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Ligament calcification									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Meniscal degeneration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tendon pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Muscle disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	10 (2.8)	14	2.8	10 (3.0)	12	2.7	8 (2.2)	9	1.8
Missing	1 (4.3)	1	8.5	0			0		
Muscle spasms									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	6 (1.7)	7	1.4	5 (1.5)	5	1.1	2 (0.5)	2	0.4
Myalgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	7	1.4	5 (1.5)	7	1.5	4 (1.1)	5	1.0
Missing	1 (4.3)	1	8.5	0			0		
Diastasis recti abdominis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Muscular weakness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Bone disorders (excl congenital and fractures)									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	5 (1.4)	5	1.0	2 (0.6)	3	0.7	4 (1.1)	4	0.8
Osteoporosis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Bone lesion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Exostosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Osteopenia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Bone pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Metatarsalgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Osteitis									
>= 20% Weight loss	0			0			0		

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Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Synovial and bursal disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	5 (1.4)	6	1.2
Bursitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	5 (1.4)	6	1.2
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	4 (1.1)	4	0.8	3 (0.9)	3	0.7	8 (2.2)	9	1.8
Intervertebral disc protrusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	3 (0.9)	3	0.7	3 (0.8)	3	0.6
Foot deformity									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	2	0.4
Intervertebral disc degeneration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Scoliosis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Spinal flattening									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Spondylolisthesis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Connective tissue disorders (excl congenital)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Polymyalgia rheumatica									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Skin and subcutaneous tissue disorders									
>= 20% Weight loss	4 (21.1)	4	15.0	8 (15.7)	10	13.8	1 (16.7)	1	12.6
< 20% Weight loss	32 (8.9)	36	7.3	29 (8.6)	40	8.8	36 (9.8)	41	8.1
Missing	2 (8.7)	3	25.5	3 (20.0)	4	48.9	0		
Epidermal and dermal conditions									
>= 20% Weight loss	3 (15.8)	3	11.3	5 (9.8)	6	8.3	1 (16.7)	1	12.6
< 20% Weight loss	19 (5.3)	20	4.1	20 (5.9)	27	6.0	21 (5.7)	22	4.4
Missing	1 (4.3)	2	17.0	2 (13.3)	2	24.5	0		
Drug eruption									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			3 (0.8)	4	0.8
Missing	0			1 (6.7)	1	12.2	0		
Perioral dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Dry skin									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Rash pruritic									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Missing	1 (4.3)	2	17.0	0			0		
Rash									
>= 20% Weight loss	3 (15.8)	3	11.3	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	7 (2.1)	10	2.2	4 (1.1)	4	0.8
Dermatitis contact									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Psoriasis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Skin burning sensation									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Eczema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	4 (1.2)	4	0.9	2 (0.5)	2	0.4
Blister									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	3	0.7	0		
Decubitus ulcer									
>= 20% Weight loss	0			0			0		

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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Dermatitis allergic												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Intertrigo												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Pain of skin												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Pruritus												
>= 20% Weight loss	0				0				1	(16.7)	1	12.6
< 20% Weight loss	2	(0.6)	2	0.4	1	(0.3)	1	0.2	2	(0.5)	2	0.4
Sensitive skin												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Skin exfoliation												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Skin lesion												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	2	(0.6)	2	0.4	1	(0.3)	1	0.2	1	(0.3)	1	0.2
Dermatitis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	2	(0.6)	2	0.4	0				2	(0.5)	2	0.4
Erythema												
>= 20% Weight loss	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	2	0.4	0			0		
Neurodermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Parapsoriasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Rash erythematous									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Stasis dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Xanthelasma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Skin appendage conditions									
>= 20% Weight loss	1 (5.3)	1	3.8	2 (3.9)	3	4.1	0		
< 20% Weight loss	9 (2.5)	9	1.8	6 (1.8)	7	1.5	8 (2.2)	8	1.6
Missing	1 (4.3)	1	8.5	1 (6.7)	2	24.5	0		
Hyperhidrosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			3 (0.8)	3	0.6
Missing	0			1 (6.7)	2	24.5	0		
Alopecia									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	2	2.8	0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	1 (4.3)	1	8.5	0			0		
Ingrowing nail									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			2 (0.5)	2	0.4
Acne									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Alopecia areata									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Onychomadesis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Miliaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Nail dystrophy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Cutaneous neoplasms benign									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			3 (0.8)	4	0.8
Dermal cyst									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			3 (0.8)	4	0.8
Angioedema and urticaria									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Urticaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Chronic spontaneous urticaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Cornification and dystrophic skin disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Actinic keratosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Dermatitis papillaris capillitii									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Hyperkeratosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Punctate keratosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Skin and subcutaneous tissue disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	4	0.9	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetic foot									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	3	0.7	0		
Skin ulcer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Skin vascular abnormalities									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Ecchymosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Haemorrhage subcutaneous									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
General disorders and administration site conditions									
>= 20% Weight loss	4 (21.1)	7	26.3	9 (17.6)	11	15.2	1 (16.7)	1	12.6
< 20% Weight loss	46 (12.8)	61	12.4	59 (17.5)	80	17.7	43 (11.7)	58	11.5
Missing	1 (4.3)	1	8.5	1 (6.7)	2	24.5	2 (7.4)	2	12.5
General system disorders NEC									
>= 20% Weight loss	4 (21.1)	6	22.5	7 (13.7)	9	12.4	1 (16.7)	1	12.6
< 20% Weight loss	35 (9.7)	45	9.2	49 (14.5)	57	12.6	26 (7.0)	28	5.6
Missing	1 (4.3)	1	8.5	1 (6.7)	2	24.5	1 (3.7)	1	6.2
Fatigue									
>= 20% Weight loss	2 (10.5)	2	7.5	4 (7.8)	4	5.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	17 (4.7)	24	4.9	23 (6.8)	24	5.3	4 (1.1)	4	0.8
Missing	0			1 (6.7)	1	12.2	0		
Influenza like illness									
>= 20% Weight loss	0			1 (2.0)	2	2.8	0		
< 20% Weight loss	1 (0.3)	1	0.2	3 (0.9)	3	0.7	3 (0.8)	3	0.6
Missing	0			1 (6.7)	1	12.2	0		
Asthenia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	4 (1.1)	4	0.8	6 (1.8)	7	1.5	1 (0.3)	1	0.2
Peripheral swelling									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	4 (1.1)	4	0.8
Feeling cold									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Early satiety									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	4 (1.2)	4	0.9	2 (0.5)	2	0.4
Malaise									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	4 (1.2)	4	0.9	1 (0.3)	1	0.2
Non-cardiac chest pain									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		
Pain									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	2 (0.5)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2
Oedema peripheral									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	3 (0.8)	3	0.6
Chest discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Chest pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	3 (0.8)	4	0.8
Face oedema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hunger									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Swelling									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Thirst decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Chills									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Discomfort									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Inflammation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Polyp									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	0			0			0		
Sensation of foreign body									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Thirst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Administration site reactions									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	6 (1.7)	7	1.4	12 (3.6)	18	4.0	10 (2.7)	18	3.6
Injection site pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	7 (2.1)	9	2.0	3 (0.8)	7	1.4
Implant site pain									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Injection site erythema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		
Injection site bruising									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	2	0.4	5 (1.4)	6	1.2
Injection site reaction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Injection site mass									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	1 (0.3)	1	0.2
Injection site discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Injection site haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Injection site urticaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Tissue disorders NEC									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Mass									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Nodule									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Body temperature conditions									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	9 (2.5)	9	1.8	4 (1.2)	4	0.9	8 (2.2)	11	2.2
Missing	0			0			1 (3.7)	1	6.2
Pyrexia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	9 (2.5)	9	1.8	4 (1.2)	4	0.9	8 (2.2)	11	2.2
Missing	0			0			1 (3.7)	1	6.2
Therapeutic and nontherapeutic effects (excl toxicity)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Drug intolerance									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Complications associated with device									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Complication associated with device									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Metabolism and nutrition disorders									
>= 20% Weight loss	5 (26.3)	9	33.8	9 (17.6)	10	13.8	1 (16.7)	1	12.6
< 20% Weight loss	42 (11.7)	58	11.8	46 (13.6)	55	12.2	48 (13.0)	56	11.1
Missing	1 (4.3)	1	8.5	1 (6.7)	1	12.2	4 (14.8)	4	24.9
Appetite and general nutritional disorders									
>= 20% Weight loss	4 (21.1)	6	22.5	7 (13.7)	8	11.0	1 (16.7)	1	12.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	28 (7.8)	34	6.9	34 (10.1)	38	8.4	15 (4.1)	17	3.4
Decreased appetite									
>= 20% Weight loss	3 (15.8)	5	18.8	7 (13.7)	8	11.0	0		
< 20% Weight loss	26 (7.2)	29	5.9	31 (9.2)	33	7.3	15 (4.1)	17	3.4
Hyperphagia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Increased appetite									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	5	1.0	1 (0.3)	1	0.2	0		
Overweight									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Cachexia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Obesity									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Acid-base disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Missing	0			1 (6.7)	1	12.2	0		
Ketoacidosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lactic acidosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Electrolyte and fluid balance conditions									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	4 (1.1)	5	1.0	6 (1.8)	6	1.3	2 (0.5)	2	0.4
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2
Hypokalaemia									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	2	0.4	2 (0.6)	2	0.4	0		
Dehydration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	1 (0.3)	1	0.2
Missing	1 (4.3)	1	8.5	0			1 (3.7)	1	6.2
Hyponatraemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Hyperkalaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Diabetic complications									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Diabetic ketoacidosis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetic metabolic decompensation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Lipid metabolism disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	5 (1.5)	5	1.1	9 (2.4)	9	1.8
Dyslipidaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	6 (1.6)	6	1.2
Hyperlipidaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Hypertriglyceridaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Hypercholesterolaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Purine and pyrimidine metabolism disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	4	0.8	2 (0.6)	2	0.4	3 (0.8)	5	1.0
Gout									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	4	0.8	2 (0.6)	2	0.4	2 (0.5)	4	0.8
Hyperuricaemia									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Vitamin related disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Folate deficiency									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Vitamin B complex deficiency									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Vitamin D deficiency									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Bone, calcium, magnesium and phosphorus metabolism disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	1 (0.3)	1	0.2	3 (0.8)	3	0.6
Missing	0			0			1 (3.7)	1	6.2
Hypomagnesaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Hypercalcaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Missing	0			0			1 (3.7)	1	6.2
Hypercalcitoninaemia									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Hypocalcaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Glucose metabolism disorders (incl diabetes mellitus)									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	3	0.6	1 (0.3)	1	0.2	18 (4.9)	18	3.6
Missing	0			0			2 (7.4)	2	12.5
Diabetes mellitus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	5 (1.4)	5	1.0
Missing	0			0			1 (3.7)	1	6.2
Diabetes mellitus inadequate control									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	0			5 (1.4)	5	1.0
Hyperglycaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			4 (1.1)	4	0.8
Missing	0			0			1 (3.7)	1	6.2
Hyperinsulinaemia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Hypoglycaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Type 2 diabetes mellitus									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Iron and trace metal metabolism disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Iron deficiency									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Metabolism disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	0			0		
Hyperamylasaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Hyperlipasaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Injury, poisoning and procedural complications									
>= 20% Weight loss	1 (5.3)	1	3.8	10 (19.6)	13	17.9	1 (16.7)	1	12.6
< 20% Weight loss	48 (13.3)	68	13.8	37 (11.0)	47	10.4	47 (12.7)	59	11.7
Missing	2 (8.7)	2	17.0	1 (6.7)	8	97.8	1 (3.7)	1	6.2
Injuries NEC									
>= 20% Weight loss	1 (5.3)	1	3.8	7 (13.7)	8	11.0	0		
< 20% Weight loss	35 (9.7)	47	9.6	24 (7.1)	28	6.2	36 (9.8)	40	7.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	1 (4.3)	1	8.5	1 (6.7)	3	36.7	0		
Muscle strain									
>= 20% Weight loss	0			4 (7.8)	4	5.5	0		
< 20% Weight loss	5 (1.4)	5	1.0	4 (1.2)	4	0.9	1 (0.3)	1	0.2
Skin laceration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Missing	0			1 (6.7)	1	12.2	0		
Road traffic accident									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Missing	0			1 (6.7)	1	12.2	0		
Traumatic haemothorax									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Fall									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	8 (2.2)	8	1.6	4 (1.2)	5	1.1	2 (0.5)	3	0.6
Arthropod sting									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Head injury									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Post-traumatic pain									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			0		
Ligament sprain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	6 (1.7)	8	1.6	3 (0.9)	3	0.7	6 (1.6)	6	1.2
Limb injury									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	0		
Bone contusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Contusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	3	0.7	8 (2.2)	9	1.8
Animal bite									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Epicondylitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Face injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Muscle injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Skin abrasion									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Tooth fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	1 (0.3)	1	0.2	3 (0.8)	3	0.6
Abdominal injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Arthropod bite									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Chest injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Craniocerebral injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Foreign body in eye									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Injury corneal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Ligament rupture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Missing	1 (4.3)	1	8.5	0			0		
Muscle rupture									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Post-traumatic neck syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Soft tissue injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	5	1.0	0			0		
Spinal column injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Subdural haematoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Tendon injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Tendon rupture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Wound									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Bone and joint injuries									
>= 20% Weight loss	0			3 (5.9)	3	4.1	1 (16.7)	1	12.6
< 20% Weight loss	7 (1.9)	8	1.6	10 (3.0)	11	2.4	12 (3.3)	12	2.4
Missing	1 (4.3)	1	8.5	1 (6.7)	5	61.1	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Rib fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3	(0.9)	3 0.7	0		
Missing	0			1	(6.7)	1 12.2	0		
Cervical vertebral fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1	(6.7)	1 12.2	0		
Spinal compression fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1	(6.7)	1 12.2	0		
Thoracic vertebral fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1	(6.7)	1 12.2	0		
Upper limb fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1	(6.7)	1 12.2	0		
Foot fracture									
>= 20% Weight loss	0			1	(2.0)	1 1.4	0		
< 20% Weight loss	0			3	(0.9)	3 0.7	3	(0.8)	3 0.6
Meniscus injury									
>= 20% Weight loss	0			1	(2.0)	1 1.4	0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Radius fracture									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Humerus fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	0		
Joint injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	5 (1.4)	5	1.0
Stress fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Wrist fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ankle fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	1 (4.3)	1	8.5	0			0		
Bone fissure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Cartilage injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Hand fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Hip fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Joint dislocation									
>= 20% Weight loss	0			0			1	(16.7)	1 12.6
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Lisfranc fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Spinal fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Sternal fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Procedural related injuries and complications NEC									
>= 20% Weight loss	0			1	(2.0)	1 1.4	0		
< 20% Weight loss	2	(0.6)	2 0.4	4	(1.2)	4 0.9	4	(1.1)	4 0.8
Missing	0			0			1	(3.7)	1 6.2
Graft complication									
>= 20% Weight loss	0			1	(2.0)	1 1.4	0		
< 20% Weight loss	0			0			0		
Post procedural haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2	(0.6)	2 0.4	0		
Anaemia postoperative									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Procedural pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Dental restoration failure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Incision site pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Post procedural complication									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Surgical skin tear									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Medication errors and other product use errors and issues									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	5 (1.4)	8	1.6	1 (0.3)	1	0.2	2 (0.5)	3	0.6
Accidental overdose									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	5	1.0	0			2 (0.5)	3	0.6
Extra dose administered									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Dose calculation error									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Incorrect dose administered									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	0			0		
Injuries by physical agents									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	0		
Hypobarism									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Sunburn									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Thermal burn									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Heat illness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Overdoses and underdoses NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Intentional overdose									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Respiratory, thoracic and mediastinal disorders									
>= 20% Weight loss	5 (26.3)	8	30.0	6 (11.8)	7	9.6	2 (33.3)	2	25.2
< 20% Weight loss	28 (7.8)	33	6.7	39 (11.6)	51	11.3	31 (8.4)	38	7.5
Missing	3 (13.0)	3	25.5	2 (13.3)	4	48.9	3 (11.1)	3	18.7
Respiratory tract signs and symptoms									
>= 20% Weight loss	2 (10.5)	2	7.5	4 (7.8)	4	5.5	0		
< 20% Weight loss	10 (2.8)	10	2.0	14 (4.2)	14	3.1	9 (2.4)	9	1.8
Missing	1 (4.3)	1	8.5	1 (6.7)	1	12.2	0		
Hiccups									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Missing	0			1 (6.7)	1	12.2	0		
Oropharyngeal pain									
>= 20% Weight loss	2 (10.5)	2	7.5	2 (3.9)	2	2.8	0		
< 20% Weight loss	5 (1.4)	5	1.0	5 (1.5)	5	1.1	6 (1.6)	6	1.2
Missing	1 (4.3)	1	8.5	0			0		
Dysphonia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Aphonia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Rhinorrhoea									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	3 (0.8)	3	0.6	4 (1.2)	4	0.9	0		
Dry throat									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Oropharyngeal discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Painful respiration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Upper respiratory tract congestion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Nasal discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Upper-airway cough syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Respiratory disorders NEC									
>= 20% Weight loss	2 (10.5)	2	7.5	0			2 (33.3)	2	25.2
< 20% Weight loss	12 (3.3)	13	2.6	17 (5.0)	18	4.0	12 (3.3)	15	3.0
Missing	2 (8.7)	2	17.0	1 (6.7)	1	12.2	1 (3.7)	1	6.2
Acute respiratory failure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Missing	0			1 (6.7)	1	12.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cough									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	9 (2.5)	10	2.0	9 (2.7)	9	2.0	7 (1.9)	8	1.6
Missing	1 (4.3)	1	8.5	0			0		
Productive cough									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		
Missing	1 (4.3)	1	8.5	0			0		
Pulmonary mass									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		
Respiratory disorder									
>= 20% Weight loss	1 (5.3)	1	3.8	0			1 (16.7)	1	12.6
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Sleep apnoea syndrome									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	3 (0.8)	3	0.6
Dyspnoea									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Missing	0			0			1 (3.7)	1	6.2
Hypoxia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Bronchial disorders (excl neoplasms)									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	5 (1.4)	5	1.0	5 (1.5)	7	1.5	6 (1.6)	6	1.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	0			1 (6.7)	1	12.2	0		
Asthma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	4 (1.2)	5	1.1	3 (0.8)	3	0.6
Missing	0			1 (6.7)	1	12.2	0		
Bronchospasm									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Chronic obstructive pulmonary disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Childhood asthma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Pleural disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Pneumothorax									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Upper respiratory tract disorders (excl infections)									
>= 20% Weight loss	2 (10.5)	2	7.5	1 (2.0)	1	1.4	0		
< 20% Weight loss	4 (1.1)	5	1.0	9 (2.7)	11	2.4	7 (1.9)	8	1.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	0			0			1 (3.7)	1	6.2
Sinus congestion									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Epistaxis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			4 (1.2)	5	1.1	4 (1.1)	4	0.8
Missing	0			0			1 (3.7)	1	6.2
Rhinitis allergic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	3 (0.9)	3	0.7	0		
Nasal congestion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	3	0.6	2 (0.6)	2	0.4	2 (0.5)	3	0.6
Lower respiratory tract disorders (excl obstruction and infection)									
>= 20% Weight loss	1 (5.3)	2	7.5	1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Idiopathic interstitial pneumonia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Atelectasis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Emphysema									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Eye disorders									
>= 20% Weight loss	5 (26.3)	7	26.3	5 (9.8)	8	11.0	1 (16.7)	1	12.6
< 20% Weight loss	41 (11.4)	58	11.8	45 (13.4)	61	13.5	40 (10.8)	54	10.7
Missing	0			0			1 (3.7)	1	6.2
Retina, choroid and vitreous haemorrhages and vascular disorders									
>= 20% Weight loss	0			4 (7.8)	5	6.9	0		
< 20% Weight loss	12 (3.3)	13	2.6	17 (5.0)	18	4.0	10 (2.7)	11	2.2
Missing	0			0			1 (3.7)	1	6.2
Diabetic retinopathy									
>= 20% Weight loss	0			4 (7.8)	4	5.5	0		
< 20% Weight loss	11 (3.1)	12	2.4	11 (3.3)	12	2.7	10 (2.7)	11	2.2
Missing	0			0			1 (3.7)	1	6.2
Retinal haemorrhage									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Non-proliferative retinopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Retinopathy hypertensive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Retinal artery occlusion									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Retinopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Eye disorders NEC									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	7 (1.9)	7	1.4	7 (2.1)	7	1.5	6 (1.6)	6	1.2
Dry eye									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	3 (0.8)	3	0.6	5 (1.5)	5	1.1	4 (1.1)	4	0.8
Lacrimation increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Vitreous disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Eyelid disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Retinal disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Ocular structural change, deposit and degeneration NEC									
>= 20% Weight loss	3 (15.8)	4	15.0	1 (2.0)	1	1.4	0		
< 20% Weight loss	7 (1.9)	8	1.6	5 (1.5)	5	1.1	3 (0.8)	4	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Detachment of retinal pigment epithelium									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Macular fibrosis									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Optic disc disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Retinal degeneration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Retinal depigmentation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Vitreous detachment									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Age-related macular degeneration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Choroidal dystrophy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Macular degeneration									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Optic atrophy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Retinal drusen									
>= 20% Weight loss	2 (10.5)	2	7.5	0			0		
< 20% Weight loss	0			0			0		
Vitreous floaters									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Anterior eye structural change, deposit and degeneration									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	7 (1.9)	7	1.4	9 (2.7)	11	2.4	12 (3.3)	15	3.0
Cataract									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	4 (1.1)	4	0.8	5 (1.5)	6	1.3	8 (2.2)	9	1.8
Cataract cortical									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cataract subcapsular									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Dermatochalasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Narrow anterior chamber angle									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Cataract nuclear									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	2	0.4
Pinguecula									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Posterior capsule opacification									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Ocular infections, irritations and inflammations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	13 (3.6)	13	2.6	8 (2.4)	10	2.2	6 (1.6)	6	1.2
Blepharitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	3	0.7	2 (0.5)	2	0.4
Macular oedema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	3	0.7	0		
Eyelid rash									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Keratitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Meibomian gland dysfunction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ocular hyperaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Conjunctivitis allergic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	0			0		
Episcleritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Eye pruritus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Punctate keratitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Swelling of eyelid									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Uveitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Ocular haemorrhages and vascular disorders NEC									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.6)	2	0.4	0			2 (0.5)	2	0.4
Eye haemorrhage									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Conjunctival haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Optic disc haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Vision disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	7 (1.9)	7	1.4	5 (1.5)	5	1.1	8 (2.2)	8	1.6
Vision blurred									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	3 (0.9)	3	0.7	2 (0.5)	2	0.4
Myopia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Visual impairment									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Astigmatism									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Hypermetropia									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Pathologic myopia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Presbyopia									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Glaucoma and ocular hypertension									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	3	0.7	2 (0.5)	2	0.4
Glaucoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	3	0.7	2 (0.5)	2	0.4
Ocular neuromuscular disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Eyelid ptosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ocular sensory symptoms NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Asthenopia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cardiac disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	3 (15.8)	4	15.0	2 (3.9)	3	4.1	1 (16.7)	1	12.6
< 20% Weight loss	17 (4.7)	20	4.1	18 (5.3)	23	5.1	11 (3.0)	14	2.8
Missing	0			2 (13.3)	2	24.5	1 (3.7)	2	12.5
Cardiac arrhythmias									
>= 20% Weight loss	2 (10.5)	2	7.5	2 (3.9)	3	4.1	1 (16.7)	1	12.6
< 20% Weight loss	8 (2.2)	10	2.0	10 (3.0)	12	2.7	3 (0.8)	4	0.8
Missing	0			1 (6.7)	1	12.2	0		
Atrial fibrillation									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	1 (0.3)	1	0.2
Missing	0			1 (6.7)	1	12.2	0		
Supraventricular extrasystoles									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			3 (0.9)	3	0.7	0		
Tachycardia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Supraventricular tachycardia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Atrioventricular block first degree									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Bundle branch block right									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Sinus tachycardia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Ventricular extrasystoles									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Atrial flutter									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	2	0.4
Bradycardia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Bundle branch block left									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Coronary artery disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	6 (1.7)	6	1.2	6 (1.8)	6	1.3	4 (1.1)	4	0.8
Missing	0			1 (6.7)	1	12.2	0		
Myocardial infarction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Missing	0			1 (6.7)	1	12.2	0		
Angina pectoris									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Acute myocardial infarction									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Angina unstable									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Coronary artery disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Myocardial ischaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Arteriosclerosis coronary artery									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Cardiac disorders, signs and symptoms NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	4	0.9	3 (0.8)	3	0.6
Missing	0			0			1 (3.7)	1	6.2
Palpitations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Cardiovascular disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	1 (0.3)	1	0.2
Hypertensive heart disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	0			0			1 (3.7)	1	6.2
Heart failures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	3	0.6
Cardiac failure congestive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Cardiac failure acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Left ventricular failure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Myocardial disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Cardiac hypertrophy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Left ventricular hypertrophy									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Vascular disorders									
>= 20% Weight loss	1 (5.3)	1	3.8	4 (7.8)	6	8.3	1 (16.7)	1	12.6

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	21 (5.8)	22	4.5	19 (5.6)	19	4.2	28 (7.6)	30	5.9
Missing	0			1 (6.7)	1	12.2	1 (3.7)	1	6.2
Vascular disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Missing	0			1 (6.7)	1	12.2	0		
Aortic rupture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (6.7)	1	12.2	0		
Aortic dilatation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hot flush									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Vascular hypertensive disorders									
>= 20% Weight loss	0			2 (3.9)	3	4.1	0		
< 20% Weight loss	9 (2.5)	9	1.8	8 (2.4)	8	1.8	15 (4.1)	16	3.2
Hypertension									
>= 20% Weight loss	0			2 (3.9)	3	4.1	0		
< 20% Weight loss	9 (2.5)	9	1.8	8 (2.4)	8	1.8	12 (3.3)	12	2.4
Hypertensive crisis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Hypertensive urgency									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Decreased and nonspecific blood pressure disorders and shock									
>= 20% Weight loss	0			2 (3.9)	3	4.1	0		
< 20% Weight loss	5 (1.4)	6	1.2	2 (0.6)	2	0.4	3 (0.8)	3	0.6
Missing	0			0			1 (3.7)	1	6.2
Hypotension									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	4 (1.1)	5	1.0	1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Orthostatic hypotension									
>= 20% Weight loss	0			1 (2.0)	2	2.8	0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Blood pressure inadequately controlled									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Shock									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Vascular haemorrhagic disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	1 (0.3)	1	0.2
Haematoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	1 (0.3)	1	0.2
Aneurysms and artery dissections									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Aortic aneurysm									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			1 (16.7)	1	12.6
< 20% Weight loss	5 (1.4)	5	1.0	1 (0.3)	1	0.2	4 (1.1)	5	1.0
Aortic arteriosclerosis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	0		
Arteriosclerosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Peripheral arterial occlusive disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Peripheral artery stenosis									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			0			0		
Peripheral coldness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Peripheral venous disease									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			0			2	(0.5)	3 0.6
Embolism and thrombosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	1	(0.3)	1 0.2
Post thrombotic syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Deep vein thrombosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Vascular infections and inflammations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Temporal arteritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Lymphatic vessel disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Lymphoedema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Venous varices									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			1	(0.3)	1 0.2
Varicose vein									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Investigations									
>= 20% Weight loss	2 (10.5)	4	15.0	3 (5.9)	4	5.5	0		
< 20% Weight loss	16 (4.4)	19	3.9	37 (11.0)	44	9.7	32 (8.7)	41	8.1
Missing	0			0			1 (3.7)	1	6.2
Cardiac and vascular investigations (excl enzyme tests)									
>= 20% Weight loss	1 (5.3)	1	3.8	2 (3.9)	2	2.8	0		
< 20% Weight loss	1 (0.3)	1	0.2	6 (1.8)	7	1.5	4 (1.1)	4	0.8
Heart rate increased									
>= 20% Weight loss	1 (5.3)	1	3.8	1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Blood pressure decreased									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Blood pressure increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cardiac murmur									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Cardiac stress test abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Carotid pulse decreased									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Electrocardiogram Q waves									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Electrocardiogram QT prolonged									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Electrocardiogram PR prolongation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Electrocardiogram ST-T segment abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Endocrine investigations (incl sex hormones)									
>= 20% Weight loss	0			2 (3.9)	2	2.8	0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Blood thyroid stimulating hormone decreased									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Blood thyroid stimulating hormone increased									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	2 (0.5)	2	0.4
Blood parathyroid hormone increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastrointestinal investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	5 (1.4)	5	1.0	6 (1.8)	6	1.3	3 (0.8)	4	0.8
Lipase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	3 (0.9)	3	0.7	2 (0.5)	2	0.4
Colonoscopy normal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Occult blood									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Occult blood positive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Amylase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Faecal volume increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Pancreatic enzymes increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
Renal and urinary tract investigations and urinalyses									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			6	(1.8)	6 1.3	0		
Glomerular filtration rate decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3	(0.9)	3 0.7	0		
Urine albumin/creatinine ratio increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2	(0.6)	2 0.4	0		
Urine albumin/creatinine ratio abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Haematology investigations (incl blood groups)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			4	(1.2)	6 1.3	1	(0.3)	1 0.2
Haemoglobin decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3	(0.9)	3 0.7	1	(0.3)	1 0.2
Haematocrit decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2	(0.6)	2 0.4	0		
Platelet count decreased									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Enzyme investigations NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	1 (0.3)	1	0.2
Blood creatine phosphokinase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	1 (0.3)	1	0.2
Hepatobiliary investigations									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	7 (1.9)	10	2.0
Hepatic enzyme increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Liver function test abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Liver function test increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Alanine aminotransferase increased									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			4 (1.1)	4	0.8
Aspartate aminotransferase increased									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Blood bilirubin increased									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Transaminases increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Lipid analyses									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2	(0.6)	2 0.4	2	(0.5)	2 0.4
Lipids abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Low density lipoprotein increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Blood cholesterol increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Blood triglycerides increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Investigations, imaging and histopathology procedures NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Endoscopy abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolic, nutritional and blood gas investigations									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	8 (2.2)	9	1.8
Vitamin B12 decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Blood glucose decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Blood glucose increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			4 (1.1)	4	0.8
Blood uric acid increased									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Brain natriuretic peptide increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Glycosylated haemoglobin increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			3 (0.8)	3	0.6
Microbiology and serology investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Helicobacter test positive									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Neurological, special senses and psychiatric investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Intraocular pressure increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	0		
Physical examination and organ system status topics									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Weight decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Weight increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Protein and chemistry analyses NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	4 (1.1)	4	0.8
C-reactive protein increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	4 (1.1)	4	0.8

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Reproductive organ and breast investigations (excl hormone analyses)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Mammogram abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Water, electrolyte and mineral investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Blood potassium increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Blood potassium decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Blood sodium increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Cytogenetic investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Prostatic specific antigen increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Immunology and allergy investigations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(0.3)	1	0.2
Antinuclear antibody increased												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(0.3)	1	0.2
Psychiatric disorders												
>= 20% Weight loss	0				5	(9.8)	8	11.0	1	(16.7)	1	12.6
< 20% Weight loss	22	(6.1)	27	5.5	19	(5.6)	21	4.6	13	(3.5)	14	2.8
Missing	1	(4.3)	1	8.5	0				1	(3.7)	1	6.2
Depressed mood disorders and disturbances												
>= 20% Weight loss	0				2	(3.9)	2	2.8	0			
< 20% Weight loss	4	(1.1)	4	0.8	5	(1.5)	5	1.1	5	(1.4)	5	1.0
Missing	1	(4.3)	1	8.5	0				0			
Depressed mood												
>= 20% Weight loss	0				1	(2.0)	1	1.4	0			
< 20% Weight loss	3	(0.8)	3	0.6	3	(0.9)	3	0.7	0			
Depression												
>= 20% Weight loss	0				1	(2.0)	1	1.4	0			
< 20% Weight loss	0				1	(0.3)	1	0.2	5	(1.4)	5	1.0
Missing	1	(4.3)	1	8.5	0				0			
Anhedonia												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.3)	1	0.2	0			
Major depression												
>= 20% Weight loss	0				0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Sleep disorders and disturbances									
>= 20% Weight loss	0			1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	6 (1.7)	6	1.2	9 (2.7)	9	2.0	3 (0.8)	3	0.6
Insomnia									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	6 (1.7)	6	1.2	7 (2.1)	7	1.5	3 (0.8)	3	0.6
Abnormal dreams									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Middle insomnia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Sleep disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Anxiety disorders and symptoms									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	10 (2.8)	11	2.2	4 (1.2)	4	0.9	5 (1.4)	5	1.0
Missing	0			0			1 (3.7)	1	6.2
Anxiety									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	7 (1.9)	8	1.6	2 (0.6)	2	0.4	3 (0.8)	3	0.6
Missing	0			0			1 (3.7)	1	6.2
Anxiety disorder due to a general medical condition									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Stress									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Generalised anxiety disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Nervousness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Post-traumatic stress disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Adjustment disorders (incl subtypes)									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	0		
Adjustment disorder with depressed mood									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Grief reaction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Mood disorders and disturbances NEC									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	2	0.4	1 (0.3)	1	0.2
Irritability									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Mood altered									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	2	0.4	1 (0.3)	1	0.2
Mood swings									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Changes in physical activity									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Restlessness									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Suicidal and self-injurious behaviours NEC									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Suicidal ideation									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Psychiatric disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Mental status changes									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Sexual dysfunctions, disturbances and gender identity disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Libido decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Renal and urinary disorders									
>= 20% Weight loss	2 (10.5)	2	7.5	2 (3.9)	3	4.1	0		
< 20% Weight loss	17 (4.7)	20	4.1	29 (8.6)	34	7.5	27 (7.3)	33	6.5
Missing	0			0			1 (3.7)	1	6.2
Urinary tract signs and symptoms									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	6 (1.7)	6	1.2	17 (5.0)	17	3.8	16 (4.3)	19	3.8
Microalbuminuria									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	1 (0.3)	1	0.2
Dysuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	4 (1.1)	4	0.8
Haematuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (0.9)	3	0.7	1 (0.3)	1	0.2
Nocturia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Proteinuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Renal colic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Pollakiuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	3 (0.8)	3	0.6
Lower urinary tract symptoms									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Micturition disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	2	0.4
Polyuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Urethral pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Urinary incontinence									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Nephropathies									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	5 (1.5)	5	1.1	1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Diabetic nephropathy									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	4 (1.2)	4	0.9	1 (0.3)	1	0.2
Nephropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Renal disorders (excl nephropathies)									
>= 20% Weight loss	0			1 (2.0)	2	2.8	0		
< 20% Weight loss	5 (1.4)	5	1.0	5 (1.5)	6	1.3	6 (1.6)	6	1.2
Missing	0			0			1 (3.7)	1	6.2
Acute kidney injury									
>= 20% Weight loss	0			1 (2.0)	2	2.8	0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Missing	0			0			1 (3.7)	1	6.2
Renal cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	3 (0.8)	3	0.6
Chronic kidney disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Renal impairment									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hydronephrosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Kidney fibrosis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Urolithiases									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	5 (1.4)	6	1.2	4 (1.2)	4	0.9	6 (1.6)	6	1.2
Nephrolithiasis									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	5 (1.4)	6	1.2	2 (0.6)	2	0.4	4 (1.1)	4	0.8
Calculus urinary									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Stag horn calculus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ureterolithiasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Bladder and bladder neck disorders (excl calculi)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Bladder outlet obstruction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Hypertonic bladder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Bladder hypertrophy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Reproductive system and breast disorders									
>= 20% Weight loss	0			4 (7.8)	4	5.5	0		
< 20% Weight loss	14 (3.9)	19	3.9	8 (2.4)	8	1.8	9 (2.4)	11	2.2
Missing	1 (4.3)	1	8.5	0			0		
Menstrual cycle and uterine bleeding disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	2	0.4
Dysmenorrhoea									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Metrorrhagia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Oligomenorrhoea									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Menorrhagia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Menstruation irregular									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	2	0.4

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Vulvovaginal disorders (excl infections and inflammations)									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Vulva cyst									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Vulval disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Vulvovaginal pruritus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Vaginal disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Vaginal haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Vulvovaginal dryness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Breast disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Breast mass									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Breast cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Breast pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Menopause related conditions									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Atrophic vulvovaginitis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Sexual function and fertility disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Erectile dysfunction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	1 (0.3)	1	0.2
Reproductive tract disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Missing	1 (4.3)	1	8.5	0			0		
Pruritus genital									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	1 (4.3)	1	8.5	0			0		
Pelvic pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Uterine, pelvic and broad ligament disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Uterine polyp									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Adenomyosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Endometriosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Male reproductive tract infections and inflammations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (1.1)	4	0.8	0			1 (0.3)	1	0.2
Balanoposthitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	0			0		
Prostatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Ovarian and fallopian tube disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			0		
Haemorrhagic ovarian cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Ovarian cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Penile and scrotal disorders (excl infections and inflammations)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	2	0.4	0			0		
Penile erosion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Peyronie's disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Prostatic disorders (excl infections and inflammations)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Benign prostatic hyperplasia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			1 (0.3)	1	0.2
Testicular and epididymal disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Testicular disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Ear and labyrinth disorders									
>= 20% Weight loss	1 (5.3)	2	7.5	1 (2.0)	1	1.4	1 (16.7)	1	12.6
< 20% Weight loss	10 (2.8)	12	2.4	19 (5.6)	19	4.2	11 (3.0)	13	2.6
Inner ear and VIIIth cranial nerve disorders									
>= 20% Weight loss	1 (5.3)	2	7.5	1 (2.0)	1	1.4	0		
< 20% Weight loss	7 (1.9)	9	1.8	9 (2.7)	9	2.0	8 (2.2)	9	1.8
Vertigo positional									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			2 (0.6)	2	0.4	1 (0.3)	1	0.2
Vertigo									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	5	1.0	7 (2.1)	7	1.5	6 (1.6)	7	1.4
Motion sickness									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tinnitus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	0			1 (0.3)	1	0.2
Aural disorders NEC									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	6 (1.8)	6	1.3	3 (0.8)	3	0.6
Ear pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	5 (1.5)	5	1.1	2 (0.5)	2	0.4
Ear pruritus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Ear discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Hearing disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	3 (0.9)	3	0.7	1 (0.3)	1	0.2
Hypoacusis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Deafness bilateral									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Deafness unilateral									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Mixed deafness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
External ear disorders (excl congenital)									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Cerumen impaction									
>= 20% Weight loss	0			0			1 (16.7)	1	12.6
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Excessive cerumen production									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Blood and lymphatic system disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	9 (2.5)	9	1.8	11 (3.3)	12	2.7	8 (2.2)	9	1.8
Missing	0			0			2 (7.4)	2	12.5
Anaemias nonhaemolytic and marrow depression									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	8 (2.2)	8	1.6	9 (2.7)	10	2.2	5 (1.4)	5	1.0
Missing	0			0			1 (3.7)	1	6.2
Anaemia									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	4 (1.1)	4	0.8	8 (2.4)	8	1.8	4 (1.1)	4	0.8
Iron deficiency anaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Pancytopenia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hypochromic anaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Microcytic anaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Normocytic anaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Platelet disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Thrombocytosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Spleen, lymphatic and reticuloendothelial system disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	2 (0.5)	2	0.4
Missing	0			0			1 (3.7)	1	6.2
Splenomegaly									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Lymphadenopathy									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			2 (0.5)	2	0.4
White blood cell disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			2 (0.5)	2	0.4
Leukocytosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Lymphopenia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Hepatobiliary disorders									
>= 20% Weight loss	0			1 (2.0)	3	4.1	0		
< 20% Weight loss	10 (2.8)	11	2.2	9 (2.7)	10	2.2	8 (2.2)	12	2.4
Missing	0			0			1 (3.7)	2	12.5
Hepatic and hepatobiliary disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	6 (1.7)	6	1.2	7 (2.1)	8	1.8	8 (2.2)	8	1.6
Missing	0			0			1 (3.7)	2	12.5
Hepatic steatosis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	5 (1.4)	5	1.0
Hepatic cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Hepatic lesion									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Non-alcoholic steatohepatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Nonalcoholic fatty liver disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	1	(0.3)	1 0.2	0		
Portal vein thrombosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Missing	0			0			1	(3.7)	1 6.2
Drug-induced liver injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Hepatic cirrhosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Hepatomegaly									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Liver disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Portal hypertension									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1	(3.7)	1 6.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gallbladder disorders									
>= 20% Weight loss	0			1 (2.0)	2	2.8	0		
< 20% Weight loss	4 (1.1)	5	1.0	2 (0.6)	2	0.4	3 (0.8)	4	0.8
Cholecystitis chronic									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	0			0			0		
Cholelithiasis									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	0			3 (0.8)	3	0.6
Gallbladder polyp									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	0		
Cholecystitis acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Immune system disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	6 (1.7)	6	1.2	5 (1.5)	5	1.1	6 (1.6)	7	1.4
Allergic conditions									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	5 (1.4)	5	1.0	5 (1.5)	5	1.1	6 (1.6)	7	1.4
Seasonal allergy									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	2 (0.6)	2	0.4	3 (0.9)	3	0.7	4 (1.1)	5	1.0
Allergy to arthropod sting									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.3)	1	0.2	1 (0.3)	1	0.2
Hypersensitivity									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Allergy to chemicals									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Drug hypersensitivity									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Multiple allergies									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Immune disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Immunisation reaction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Endocrine disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	4 (1.1)	4	0.8
Thyroid gland disorders									
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	3 (0.8)	3	0.6	3 (0.9)	3	0.7	4 (1.1)	4	0.8
Hypothyroidism									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.0)	1	1.4	0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Primary hyperthyroidism									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Thyroid cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Autoimmune thyroiditis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			1 (0.3)	1	0.2
Goitre									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Silent thyroiditis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Thyroid mass									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
>= 20% Weight loss	2 (10.5)	5	18.8	0			0		
< 20% Weight loss	11 (3.1)	11	2.2	9 (2.7)	10	2.2	10 (2.7)	12	2.4
Missing	0			0			2 (7.4)	2	12.5
Gastrointestinal neoplasms benign									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	2 (0.6)	2	0.4	2 (0.5)	2	0.4
Benign duodenal neoplasm									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal tract adenoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Colon adenoma									
>= 20% Weight loss	1 (5.3)	2	7.5	0			0		
< 20% Weight loss	2 (0.6)	2	0.4	0			2 (0.5)	2	0.4
Leukaemias									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (0.6)	2	0.4	0		
Chronic lymphocytic leukaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Myeloid leukaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Cutaneous neoplasms benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Anogenital warts									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	0		
Melanocytic naevus									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Lymphomas non-Hodgkin's unspecified histology									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Gastrointestinal lymphoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Miscellaneous and site unspecified neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Squamous cell carcinoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Respiratory and mediastinal neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Missing	0			0			1 (3.7)	1	6.2
Nasal cavity cancer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Keratinising squamous cell carcinoma of nasopharynx									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			0		
Missing	0			0			1 (3.7)	1	6.2
Skeletal neoplasms benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Osteochondroma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.3)	1	0.2	0		
Soft tissue neoplasms benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Lipoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	1 (0.3)	1	0.2	1 (0.3)	1	0.2
Breast neoplasms malignant and unspecified (incl nipple)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Invasive ductal breast carcinoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Endocrine neoplasms benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Pituitary tumour benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Endocrine neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Neuroendocrine tumour									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastrointestinal neoplasms malignant and unspecified									
>= 20% Weight loss	2 (10.5)	2	7.5	0			0		
< 20% Weight loss	3 (0.8)	3	0.6	0			2 (0.5)	2	0.4
Adenocarcinoma gastric									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Adenocarcinoma of colon									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Gastric cancer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gastric cancer stage IV									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Gastrointestinal stromal tumour									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Gastrointestinal submucosal tumour									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			
Oral neoplasm												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			
Hepatobiliary neoplasms malignant and unspecified												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				0			
Missing	0				0				1	(3.7)	1	6.2
Hepatocellular carcinoma												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				0			
Missing	0				0				1	(3.7)	1	6.2
Metastases												
>= 20% Weight loss	1	(5.3)	1	3.8	0				0			
< 20% Weight loss	0				0				0			
Metastases to liver												
>= 20% Weight loss	1	(5.3)	1	3.8	0				0			
< 20% Weight loss	0				0				0			
Reproductive neoplasms female benign												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			
Uterine leiomyoma												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(0.3)	1	0.2	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Reproductive neoplasms female malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Uterine cancer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Reproductive neoplasms male malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Prostate cancer									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Skin neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Basal cell carcinoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Surgical and medical procedures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (0.8)	3	0.6	1 (0.3)	1	0.2	5 (1.4)	6	1.2
Endocrine gland therapeutic procedures									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E R	N	(%)	E R	N	(%)	E R
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Thyroidectomy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1	(0.3)	1 0.2	0		
Bone and joint therapeutic procedures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			1	(0.3)	1 0.2
Bone graft									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Joint injection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Cardiac therapeutic procedures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Cardiac pacemaker replacement									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1	(0.3)	1 0.2	0			0		
Eye therapeutic procedures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Cataract operation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1	(0.3)	1 0.2
Head and neck therapeutic procedures									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Tooth extraction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (0.3)	1	0.2	0			0		
Male genital tract therapeutic procedures									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Sperm aspiration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Therapeutic procedures and supportive care NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			3 (0.8)	3	0.6
Cyst removal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Nerve block									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Stent placement									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Congenital, familial and genetic disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Reproductive tract and breast disorders congenital									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Phimosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (0.5)	2	0.4
Respiratory disorders congenital									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Laryngeal web									
>= 20% Weight loss	1 (5.3)	1	3.8	0			0		
< 20% Weight loss	0			0			0		
Pregnancy, puerperium and perinatal conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Abortions and stillbirth									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Abortion spontaneous									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (0.3)	1	0.2
Social circumstances									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 2

	Sema 1.0 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	2	(0.6)	2	0.4	0				0			
Economic and housing issues												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	2	(0.6)	2	0.4	0				0			
Stress at work												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	2	(0.6)	2	0.4	0				0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 22.1

55 Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N	PYE			N	PYE			N	PYE		
>= 20% Weight loss	11	15.7			38	53.7			2	2.8		
< 20% Weight loss	86	119.4			155	216.1			98	137.9		
Missing	3	1.2			6	5.2			1	1.1		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Events												
>= 20% Weight loss	8	(72.7)	36	229.2	36	(94.7)	153	284.8	2	(100)	4	140.8
< 20% Weight loss	72	(83.7)	444	372.0	130	(83.9)	666	308.2	77	(78.6)	230	166.8
Missing	2	(66.7)	3	260.3	5	(83.3)	15	288.4	1	(100)	1	89.7
Serious												
Yes												
>= 20% Weight loss	0				2	(5.3)	3	5.6	0			
< 20% Weight loss	7	(8.1)	10	8.4	7	(4.5)	8	3.7	6	(6.1)	6	4.4
Missing	0				1	(16.7)	1	19.2	1	(100)	1	89.7
No												
>= 20% Weight loss	8	(72.7)	36	229.2	36	(94.7)	150	279.2	2	(100)	4	140.8
< 20% Weight loss	72	(83.7)	434	363.6	129	(83.2)	658	304.5	76	(77.6)	224	162.5
Missing	2	(66.7)	3	260.3	5	(83.3)	14	269.1	0			
Severity												
Severe												
>= 20% Weight loss	0				1	(2.6)	2	3.7	0			
< 20% Weight loss	3	(3.5)	3	2.5	1	(0.6)	1	0.5	4	(4.1)	4	2.9
Missing	0				1	(16.7)	1	19.2	1	(100)	1	89.7
Moderate												
>= 20% Weight loss	0				5	(13.2)	8	14.9	0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Severity												
Moderate												
< 20% Weight loss	14	(16.3)	63	52.8	20	(12.9)	34	15.7	11	(11.2)	13	9.4
Missing	0				0				0			
Mild												
>= 20% Weight loss	8	(72.7)	36	229.2	36	(94.7)	143	266.2	2	(100)	4	140.8
< 20% Weight loss	69	(80.2)	378	316.7	127	(81.9)	631	292.0	74	(75.5)	213	154.5
Missing	2	(66.7)	3	260.3	5	(83.3)	14	269.1	0			
Relationship to trial product												
Missing												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Missing	0				0				0			
Probable												
>= 20% Weight loss	3	(27.3)	4	25.5	8	(21.1)	29	54.0	1	(50.0)	1	35.2
< 20% Weight loss	22	(25.6)	57	47.8	44	(28.4)	124	57.4	8	(8.2)	14	10.2
Missing	0				3	(50.0)	5	96.1	1	(100)	1	89.7
Possible												
>= 20% Weight loss	6	(54.5)	17	108.3	16	(42.1)	30	55.8	0			
< 20% Weight loss	47	(54.7)	171	143.3	67	(43.2)	173	80.1	10	(10.2)	17	12.3
Missing	2	(66.7)	2	173.5	1	(16.7)	3	57.7	0			
Unlikely												
>= 20% Weight loss	7	(63.6)	15	95.5	33	(86.8)	94	175.0	2	(100)	3	105.6
< 20% Weight loss	65	(75.6)	216	181.0	114	(73.5)	368	170.3	72	(73.5)	199	144.3
Missing	1	(33.3)	1	86.8	5	(83.3)	7	134.6	0			
Outcome												
Recovered												
>= 20% Weight loss	8	(72.7)	29	184.7	36	(94.7)	139	258.7	2	(100)	4	140.8

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

Adverse events by weight loss at week 68 - overview - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Outcome												
Recovered												
< 20% Weight loss	68	(79.1)	378	316.7	123	(79.4)	576	266.6	72	(73.5)	181	131.3
Missing	2	(66.7)	2	173.5	5	(83.3)	14	269.1	1	(100)	1	89.7
Recovering												
>= 20% Weight loss	1	(9.1)	2	12.7	1	(2.6)	1	1.9	0			
< 20% Weight loss	8	(9.3)	14	11.7	15	(9.7)	20	9.3	5	(5.1)	5	3.6
Missing	0				0				0			
Not Recovered												
>= 20% Weight loss	3	(27.3)	5	31.8	8	(21.1)	13	24.2	0			
< 20% Weight loss	31	(36.0)	52	43.6	45	(29.0)	70	32.4	26	(26.5)	44	31.9
Missing	1	(33.3)	1	86.8	1	(16.7)	1	19.2	0			
Leading to												
Permanent treatment discontinuation												
>= 20% Weight loss	0				1	(2.6)	2	3.7	0			
< 20% Weight loss	3	(3.5)	6	5.0	3	(1.9)	6	2.8	1	(1.0)	1	0.7
Missing	0				1	(16.7)	1	19.2	0			
Temporary interruption of trial product												
>= 20% Weight loss	0				2	(5.3)	2	3.7	0			
< 20% Weight loss	7	(8.1)	9	7.5	11	(7.1)	22	10.2	4	(4.1)	4	2.9
Missing	0				1	(16.7)	2	38.4	1	(100)	1	89.7
Dose reduction of trial product												
>= 20% Weight loss	0				4	(10.5)	5	9.3	0			
< 20% Weight loss	3	(3.5)	3	2.5	10	(6.5)	14	6.5	0			
Missing	0				0				0			

Adverse events with onset prior to randomisation are not included.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.

56 Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects and exposure	N		PYE		N		PYE		N		PYE	
>= 20% Weight loss	11		15.7		38		53.7		2		2.8	
< 20% Weight loss	86		119.4		155		216.1		98		137.9	
Missing	3		1.2		6		5.2		1		1.1	
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Adverse events												
>= 20% Weight loss	8	(72.7)	36	229.2	36	(94.7)	153	284.8	2	(100)	4	140.8
< 20% Weight loss	72	(83.7)	444	372.0	130	(83.9)	666	308.2	77	(78.6)	230	166.8
Missing	2	(66.7)	3	260.3	5	(83.3)	15	288.4	1	(100)	1	89.7
Gastrointestinal disorders												
>= 20% Weight loss	7	(63.6)	14	89.1	23	(60.5)	64	119.1	1	(50.0)	1	35.2
< 20% Weight loss	56	(65.1)	241	201.9	92	(59.4)	271	125.4	28	(28.6)	41	29.7
Missing	1	(33.3)	1	86.8	3	(50.0)	8	153.8	1	(100)	1	89.7
Gastrointestinal motility and defaecation conditions												
>= 20% Weight loss	5	(45.5)	6	38.2	19	(50.0)	22	40.9	0			
< 20% Weight loss	36	(41.9)	78	65.4	58	(37.4)	95	44.0	9	(9.2)	9	6.5
Missing	0				1	(16.7)	2	38.4	0			
Constipation												
>= 20% Weight loss	2	(18.2)	3	19.1	14	(36.8)	15	27.9	0			
< 20% Weight loss	17	(19.8)	19	15.9	37	(23.9)	43	19.9	3	(3.1)	3	2.2
Missing	0				1	(16.7)	2	38.4	0			
Diarrhoea												
>= 20% Weight loss	3	(27.3)	3	19.1	6	(15.8)	6	11.2	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	19 (22.1)	56	46.9	26 (16.8)	46	21.3	6 (6.1)	6	4.4
Gastrooesophageal reflux disease									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	5 (3.2)	5	2.3	0		
Gastrointestinal motility disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Irritable bowel syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Gastrointestinal signs and symptoms									
>= 20% Weight loss	4 (36.4)	7	44.6	12 (31.6)	31	57.7	1 (50.0)	1	35.2
< 20% Weight loss	34 (39.5)	143	119.8	57 (36.8)	133	61.5	10 (10.2)	16	11.6
Missing	1 (33.3)	1	86.8	2 (33.3)	5	96.1	0		
Nausea									
>= 20% Weight loss	1 (9.1)	1	6.4	3 (7.9)	11	20.5	1 (50.0)	1	35.2
< 20% Weight loss	16 (18.6)	25	20.9	31 (20.0)	53	24.5	3 (3.1)	3	2.2
Missing	1 (33.3)	1	86.8	1 (16.7)	2	38.4	0		
Vomiting									
>= 20% Weight loss	1 (9.1)	1	6.4	1 (2.6)	1	1.9	0		
< 20% Weight loss	9 (10.5)	33	27.6	15 (9.7)	26	12.0	2 (2.0)	2	1.5
Missing	0			1 (16.7)	2	38.4	0		
Dyspepsia									
>= 20% Weight loss	0			2 (5.3)	5	9.3	0		
< 20% Weight loss	6 (7.0)	17	14.2	6 (3.9)	8	3.7	1 (1.0)	4	2.9
Missing	0			1 (16.7)	1	19.2	0		
Abdominal discomfort									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	2 (18.2)	2	12.7	3 (7.9)	5	9.3	0		
< 20% Weight loss	9 (10.5)	10	8.4	9 (5.8)	11	5.1	1 (1.0)	1	0.7
Abdominal pain upper									
>= 20% Weight loss	0			3 (7.9)	6	11.2	0		
< 20% Weight loss	3 (3.5)	5	4.2	7 (4.5)	7	3.2	1 (1.0)	1	0.7
Abdominal pain									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	3 (3.5)	4	3.4	11 (7.1)	15	6.9	0		
Abdominal distension									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	7 (8.1)	8	6.7	6 (3.9)	7	3.2	2 (2.0)	3	2.2
Faeces soft									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Eructation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (4.7)	21	17.6	2 (1.3)	2	0.9	0		
Abdominal tenderness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Faeces hard									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Flatulence									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	18	15.1	1 (0.6)	1	0.5	0		
Abdominal pain lower									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (9.1)	2	12.7	0			0		
< 20% Weight loss	0			0			1 (1.0)	2	1.5
Epigastric discomfort									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Gastrointestinal inflammatory conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	9 (5.8)	10	4.6	5 (5.1)	5	3.6
Missing	0			1 (16.7)	1	19.2	0		
Colitis ischaemic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			1 (16.7)	1	19.2	0		
Enterocolitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	4 (2.6)	4	1.9	1 (1.0)	1	0.7
Gastritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (1.9)	3	1.4	3 (3.1)	3	2.2
Chronic gastritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Colitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Enteritis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Dental and gingival conditions									
>= 20% Weight loss	1 (9.1)	1	6.4	4 (10.5)	4	7.4	0		
< 20% Weight loss	5 (5.8)	5	4.2	10 (6.5)	11	5.1	6 (6.1)	6	4.4
Dental caries									
>= 20% Weight loss	1 (9.1)	1	6.4	3 (7.9)	3	5.6	0		
< 20% Weight loss	3 (3.5)	3	2.5	8 (5.2)	9	4.2	5 (5.1)	5	3.6
Tooth impacted									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Toothache									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	1 (1.0)	1	0.7
Dental cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Gastrointestinal conditions NEC									
>= 20% Weight loss	0			3 (7.9)	3	5.6	0		
< 20% Weight loss	4 (4.7)	4	3.4	7 (4.5)	9	4.2	1 (1.0)	1	0.7
Food poisoning									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Gastrointestinal disorder									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	5	2.3	0		
Gastric disorder									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	3	1.4	0		
Barrett's oesophagus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Benign neoplasms gastrointestinal									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	3 (3.5)	3	2.5	5 (3.2)	6	2.8	2 (2.0)	2	1.5
Large intestine polyp									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	3	1.4	2 (2.0)	2	1.5
Gastric polyps									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (1.9)	3	1.4	0		
Rectal polyp									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Gastrointestinal haemorrhages NEC									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Anal haemorrhage									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Mallory-Weiss syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Diverticular disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			0		
Diverticulum intestinal									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			0		
Gastrointestinal vascular conditions									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			1 (1.0)	1	0.7
Haemorrhoids									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			1 (1.0)	1	0.7
Oral soft tissue conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			3 (1.9)	3	1.4	0		
Stomatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	0		
Angular cheilitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Anal and rectal conditions NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	0		
Anal fissure									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Gastrointestinal ulceration and perforation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	1 (1.0)	1	0.7
Erosive duodenitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Gastritis erosive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Gastrointestinal stenosis and obstruction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (100)	1	89.7
Intestinal obstruction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			0		
Missing	0			0			1 (100)	1	89.7
Salivary gland conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Parotid gland enlargement									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Infections and infestations									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	4 (36.4)	4	25.5	17 (44.7)	31	57.7	0		
< 20% Weight loss	38 (44.2)	60	50.3	61 (39.4)	120	55.5	35 (35.7)	53	38.4
Missing	0			2 (33.3)	2	38.4	0		
Infections - pathogen unspecified									
>= 20% Weight loss	4 (36.4)	4	25.5	17 (44.7)	30	55.8	0		
< 20% Weight loss	35 (40.7)	54	45.2	53 (34.2)	101	46.7	34 (34.7)	51	37.0
Missing	0			1 (16.7)	1	19.2	0		
Nasopharyngitis									
>= 20% Weight loss	2 (18.2)	2	12.7	12 (31.6)	19	35.4	0		
< 20% Weight loss	22 (25.6)	34	28.5	40 (25.8)	61	28.2	18 (18.4)	24	17.4
Missing	0			1 (16.7)	1	19.2	0		
Bronchitis									
>= 20% Weight loss	0			3 (7.9)	3	5.6	0		
< 20% Weight loss	3 (3.5)	3	2.5	3 (1.9)	6	2.8	0		
Gastroenteritis									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	6 (7.0)	7	5.9	11 (7.1)	13	6.0	1 (1.0)	1	0.7
Cystitis									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	2	1.5
Rhinitis									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	2 (2.0)	2	1.5
Acute sinusitis									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Pyelonephritis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Urinary tract infection									
>= 20% Weight loss	0			1 (2.6)	3	5.6	0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Pharyngitis									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	4	1.9	4 (4.1)	5	3.6
Conjunctivitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	3	1.4	2 (2.0)	2	1.5
Tonsillitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	3 (3.1)	4	2.9
Diverticulitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Enteritis infectious									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Folliculitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	0		
Gingivitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Hordeolum									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Pelvic inflammatory disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Pyelonephritis acute									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Sinusitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	3 (3.1)	3	2.2
Urethritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Periodontitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Pyoderma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	2	1.5
Upper respiratory tract infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (2.0)	3	2.2
Vaginal infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Viral infectious disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	5 (5.8)	5	4.2	11 (7.1)	12	5.6	1 (1.0)	1	0.7
Missing	0			1 (16.7)	1	19.2	0		
Influenza									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	6 (3.9)	6	2.8	1 (1.0)	1	0.7
Missing	0			1 (16.7)	1	19.2	0		
Herpes zoster									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	3 (1.9)	3	1.4	0		
Gastroenteritis viral									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	0		
Herpes simplex									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Infectious mononucleosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Bacterial infectious disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	4 (2.6)	5	2.3	1 (1.0)	1	0.7
Alpha haemolytic streptococcal infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Cellulitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Erysipelas									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	0		
Furuncle									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Helicobacter infection									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Fungal infectious disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	0		
Tinea pedis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Vulvovaginal candidiasis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Nervous system disorders									
>= 20% Weight loss	0			8 (21.1)	11	20.5	0		
< 20% Weight loss	8 (9.3)	11	9.2	25 (16.1)	39	18.0	6 (6.1)	6	4.4
Missing	0			2 (33.3)	2	38.4	0		
Headaches									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (2.3)	2	1.7	6 (3.9)	8	3.7	3 (3.1)	3	2.2
Missing	0			2 (33.3)	2	38.4	0		
Headache									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	2 (2.3)	2	1.7	6 (3.9)	8	3.7	3 (3.1)	3	2.2
Missing	0			2 (33.3)	2	38.4	0		
Neurological disorders NEC									
>= 20% Weight loss	0			6 (15.8)	9	16.8	0		
< 20% Weight loss	6 (7.0)	8	6.7	16 (10.3)	24	11.1	3 (3.1)	3	2.2
Dizziness									
>= 20% Weight loss	0			3 (7.9)	4	7.4	0		
< 20% Weight loss	3 (3.5)	5	4.2	11 (7.1)	15	6.9	0		
Dizziness postural									
>= 20% Weight loss	0			1 (2.6)	2	3.7	0		
< 20% Weight loss	0			0			0		
Dysaesthesia									
>= 20% Weight loss	0			1 (2.6)	2	3.7	0		
< 20% Weight loss	0			0			0		
Neuralgia									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Hypoaesthesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	4	1.9	0		
Dysgeusia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Neurological symptom									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Paraesthesia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Somnolence									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Taste disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Intercostal neuralgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Sensory loss									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Spinal cord and nerve root disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	3 (1.9)	3	1.4	0		
Sciatica									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	3 (1.9)	3	1.4	0		
Central nervous system vascular disorders									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Lacunar infarction									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Cranial nerve disorders (excl neoplasms)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Parosmia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Neuromuscular disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Autonomic nervous system imbalance									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Peripheral neuropathies									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Carpal tunnel syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Musculoskeletal and connective tissue disorders									
>= 20% Weight loss	2 (18.2)	2	12.7	8 (21.1)	9	16.8	1 (50.0)	1	35.2

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	22 (25.6)	32	26.8	34 (21.9)	42	19.4	23 (23.5)	33	23.9
Missing	0			1 (16.7)	1	19.2	0		
Musculoskeletal and connective tissue disorders NEC									
>= 20% Weight loss	1 (9.1)	1	6.4	4 (10.5)	4	7.4	1 (50.0)	1	35.2
< 20% Weight loss	9 (10.5)	13	10.9	17 (11.0)	18	8.3	12 (12.2)	14	10.2
Missing	0			1 (16.7)	1	19.2	0		
Back pain									
>= 20% Weight loss	1 (9.1)	1	6.4	4 (10.5)	4	7.4	0		
< 20% Weight loss	7 (8.1)	11	9.2	14 (9.0)	15	6.9	9 (9.2)	11	8.0
Missing	0			1 (16.7)	1	19.2	0		
Musculoskeletal discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Neck pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Pain in extremity									
>= 20% Weight loss	0			0			1 (50.0)	1	35.2
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Musculoskeletal pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Musculoskeletal stiffness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Joint disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	14 (16.3)	16	13.4	11 (7.1)	11	5.1	11 (11.2)	16	11.6
Periarthritis									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	3	1.4	1 (1.0)	1	0.7
Osteoarthritis									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	2 (2.0)	2	1.5
Arthralgia									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	8 (9.3)	9	7.5	5 (3.2)	5	2.3	6 (6.1)	9	6.5
Rotator cuff syndrome									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Spinal osteoarthritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Arthritis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Articular calcification									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	2	1.5
Muscle disorders									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	1 (1.2)	1	0.8	7 (4.5)	7	3.2	1 (1.0)	1	0.7
Myalgia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	3 (1.9)	3	1.4	1 (1.0)	1	0.7
Muscle spasms									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			2 (1.3)	2	0.9	0		
Fibromyalgia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Rhabdomyolysis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Spinal stenosis									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Intervertebral disc protrusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Tendon, ligament and cartilage disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	3 (1.9)	4	1.9	0		
Tendonitis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	0		
Trigger finger									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	0		
Synovial and bursal disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Bursitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Synovitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Metabolism and nutrition disorders									
>= 20% Weight loss	1 (9.1)	1	6.4	3 (7.9)	3	5.6	0		
< 20% Weight loss	5 (5.8)	5	4.2	19 (12.3)	20	9.3	8 (8.2)	11	8.0
Missing	0			1 (16.7)	1	19.2	0		
Appetite and general nutritional disorders									
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	4 (4.7)	4	3.4	10 (6.5)	10	4.6	0		
Missing	0			1 (16.7)	1	19.2	0		
Decreased appetite									
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	4 (4.7)	4	3.4	10 (6.5)	10	4.6	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Missing	0			1 (16.7)	1	19.2	0		
Metabolism disorders NEC									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Hypercreatininaemia									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Purine and pyrimidine metabolism disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	4 (2.6)	4	1.9	4 (4.1)	5	3.6
Gout									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	1 (1.0)	2	1.5
Hyperuricaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	3 (3.1)	3	2.2
Glucose metabolism disorders (incl diabetes mellitus)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	3	1.4	3 (3.1)	4	2.9
Diabetes mellitus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Type 2 diabetes mellitus									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	1 (1.0)	1	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Glucose tolerance impaired									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	2	1.5
Lipid metabolism disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	2 (2.0)	2	1.5
Dyslipidaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	2 (2.0)	2	1.5
Electrolyte and fluid balance conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Dehydration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Injury, poisoning and procedural complications									
>= 20% Weight loss	1 (9.1)	1	6.4	7 (18.4)	8	14.9	0		
< 20% Weight loss	14 (16.3)	18	15.1	18 (11.6)	18	8.3	12 (12.2)	14	10.2
Injuries NEC									
>= 20% Weight loss	0			6 (15.8)	7	13.0	0		
< 20% Weight loss	6 (7.0)	10	8.4	11 (7.1)	11	5.1	9 (9.2)	10	7.3
Arthropod sting									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Contusion									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	3 (1.9)	3	1.4	0		
Ligament sprain									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	3 (3.5)	4	3.4	2 (1.3)	2	0.9	2 (2.0)	2	1.5
Arthropod bite									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Post-traumatic neck syndrome									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			2 (2.0)	2	1.5
Subcutaneous haematoma									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Tendon rupture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Epicondylitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Limb injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Tooth fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Limb crushing injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Muscle contusion									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (2.0)	2	1.5
Muscle strain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	2	1.7	0			0		
Road traffic accident									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Skin laceration									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Subdural haematoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Medication errors and other product use errors and issues									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Accidental overdose									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Product administration error									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Bone and joint injuries									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	4 (4.7)	4	3.4	4 (2.6)	4	1.9	1 (1.0)	1	0.7
Ankle fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Meniscus injury									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Radius fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Rib fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	0		
Fracture									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Joint injury									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Injuries by physical agents									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	3	2.5	2 (1.3)	2	0.9	3 (3.1)	3	2.2
Heat stroke									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Thermal burn									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Heat illness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			2 (2.0)	2	1.5
Skin and subcutaneous tissue disorders									
>= 20% Weight loss	2 (18.2)	6	38.2	7 (18.4)	8	14.9	1 (50.0)	1	35.2
< 20% Weight loss	11 (12.8)	16	13.4	17 (11.0)	22	10.2	10 (10.2)	13	9.4
Epidermal and dermal conditions									
>= 20% Weight loss	2 (18.2)	4	25.5	5 (13.2)	5	9.3	1 (50.0)	1	35.2
< 20% Weight loss	8 (9.3)	9	7.5	12 (7.7)	14	6.5	7 (7.1)	9	6.5
Eczema									
>= 20% Weight loss	1 (9.1)	1	6.4	1 (2.6)	1	1.9	1 (50.0)	1	35.2
< 20% Weight loss	3 (3.5)	3	2.5	3 (1.9)	3	1.4	1 (1.0)	1	0.7
Pruritus									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	2 (2.0)	3	2.2
Eczema asteatotic									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Dermatitis contact									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	0			3 (3.1)	3	2.2
Dyshidrotic eczema									

Adverse events with onset prior to randomisation are not included.
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Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	3	1.4	0		
Dermatitis atopic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	2	0.9	0		
Erythema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Rash									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Stasis dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Drug eruption									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			0			0		
Dry skin									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			0			0		
Pain of skin									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			0			0		
Rash pruritic									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Seborrhoeic dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Xanthelasma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Skin appendage conditions									
>= 20% Weight loss	2 (18.2)	2	12.7	2 (5.3)	2	3.7	0		
< 20% Weight loss	2 (2.3)	2	1.7	5 (3.2)	5	2.3	2 (2.0)	2	1.5
Alopecia									
>= 20% Weight loss	2 (18.2)	2	12.7	2 (5.3)	2	3.7	0		
< 20% Weight loss	0			0			0		
Alopecia areata									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	0		
Acne									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Ingrowing nail									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Miliaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	2 (2.0)	2	1.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Cornification and dystrophic skin disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Xeroderma									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Hyperkeratosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Angioedema and urticaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	4	3.4	2 (1.3)	2	0.9	2 (2.0)	2	1.5
Urticaria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	4	3.4	2 (1.3)	2	0.9	2 (2.0)	2	1.5
General disorders and administration site conditions									
>= 20% Weight loss	1 (9.1)	3	19.1	0			0		
< 20% Weight loss	2 (2.3)	2	1.7	15 (9.7)	34	15.7	2 (2.0)	2	1.5
Missing	0			1 (16.7)	1	19.2	0		
Body temperature conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Missing	0			1 (16.7)	1	19.2	0		
Pyrexia									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	1	(0.6)	1	0.5	1	(1.0)	1	0.7
Missing	0				1	(16.7)	1	19.2	0			
General system disorders NEC												
>= 20% Weight loss	1	(9.1)	3	19.1	0				0			
< 20% Weight loss	1	(1.2)	1	0.8	11	(7.1)	18	8.3	1	(1.0)	1	0.7
Malaise												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	5	(3.2)	8	3.7	0			
Fatigue												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				3	(1.9)	3	1.4	0			
Feeling abnormal												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				2	(1.3)	2	0.9	0			
Influenza like illness												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Non-cardiac chest pain												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Oedema peripheral												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Pain												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Thirst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Hangover									
>= 20% Weight loss	1 (9.1)	3	19.1	0			0		
< 20% Weight loss	0			0			0		
Hunger									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Administration site reactions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			4 (2.6)	15	6.9	0		
Injection site erythema									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	13	6.0	0		
Injection site dermatitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Injection site discomfort									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Respiratory, thoracic and mediastinal disorders									
>= 20% Weight loss	1 (9.1)	1	6.4	3 (7.9)	3	5.6	1 (50.0)	1	35.2
< 20% Weight loss	9 (10.5)	12	10.1	21 (13.5)	24	11.1	12 (12.2)	18	13.1
Respiratory tract signs and symptoms									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	1 (50.0)	1	35.2
< 20% Weight loss	6 (7.0)	7	5.9	14 (9.0)	16	7.4	10 (10.2)	14	10.2
Upper respiratory tract inflammation									
>= 20% Weight loss	0			1 (2.6)	1	1.9	1 (50.0)	1	35.2
< 20% Weight loss	5 (5.8)	6	5.0	10 (6.5)	12	5.6	8 (8.2)	12	8.7
Oropharyngeal pain									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	2 (2.0)	2	1.5
Hiccups									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Rhinorrhoea									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Upper respiratory tract disorders (excl infections)									
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	1 (1.2)	1	0.8	5 (3.2)	5	2.3	1 (1.0)	2	1.5
Rhinitis allergic									
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	0			4 (2.6)	4	1.9	1 (1.0)	2	1.5
Epistaxis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Vasomotor rhinitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Respiratory disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	1 (1.0)	1	0.7
Cough									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Dyspnoea									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Bronchial disorders (excl neoplasms)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	3	2.5	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Asthma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Cough variant asthma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	0			1 (1.0)	1	0.7
Investigations									
>= 20% Weight loss	1 (9.1)	1	6.4	5 (13.2)	5	9.3	0		
< 20% Weight loss	11 (12.8)	14	11.7	11 (7.1)	15	6.9	9 (9.2)	11	8.0
Missing	1 (33.3)	1	86.8	0			0		
Gastrointestinal investigations									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	4 (4.7)	4	3.4	2 (1.3)	3	1.4	0		
Missing	1 (33.3)	1	86.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lipase increased									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	3 (3.5)	3	2.5	2 (1.3)	2	0.9	0		
Amylase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Missing	1 (33.3)	1	86.8	0			0		
Occult blood positive									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Cardiac and vascular investigations (excl enzyme tests)									
>= 20% Weight loss	1 (9.1)	1	6.4	2 (5.3)	2	3.7	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Blood pressure decreased									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Electrocardiogram QRS complex prolonged									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Electrocardiogram QT prolonged									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			0			0		
Enzyme investigations NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (4.7)	4	3.4	6 (3.9)	7	3.2	2 (2.0)	2	1.5

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Blood creatine phosphokinase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (4.7)	4	3.4	6 (3.9)	7	3.2	2 (2.0)	2	1.5
Endocrine investigations (incl sex hormones)									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Blood thyroid stimulating hormone decreased									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Hepatobiliary investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	5 (5.1)	5	3.6
Aspartate aminotransferase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Liver function test increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	2 (2.0)	2	1.5
Alanine aminotransferase increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (2.0)	2	1.5
Blood bilirubin increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Haematology investigations (incl blood groups)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	2	1.7	1 (0.6)	1	0.5	0		
Haemoglobin decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Lymphocyte count decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
White blood cell count increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Physical examination and organ system status topics									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Weight decreased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Lipid analyses									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Blood triglycerides increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Metabolic, nutritional and blood gas investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			2 (2.0)	2	1.5
Blood uric acid increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Glycosylated haemoglobin increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Protein and chemistry analyses NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
C-reactive protein increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Water, electrolyte and mineral investigations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Blood potassium increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Vascular disorders									
>= 20% Weight loss	0			3 (7.9)	3	5.6	0		
< 20% Weight loss	2 (2.3)	2	1.7	8 (5.2)	8	3.7	4 (4.1)	4	2.9

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Decreased and nonspecific blood pressure disorders and shock									
>= 20% Weight loss	0			3 (7.9)	3	5.6	0		
< 20% Weight loss	0			2 (1.3)	2	0.9	0		
Orthostatic hypotension									
>= 20% Weight loss	0			2 (5.3)	2	3.7	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Hypotension									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Vascular hypertensive disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	4 (2.6)	4	1.9	3 (3.1)	3	2.2
Hypertension									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	4 (2.6)	4	1.9	3 (3.1)	3	2.2
Arteriosclerosis, stenosis, vascular insufficiency and necrosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Arteriosclerosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Embolism and thrombosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Venous thrombosis limb									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Eye disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	6 (7.0)	7	5.9	16 (10.3)	18	8.3	7 (7.1)	8	5.8
Anterior eye structural change, deposit and degeneration									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Cataract									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Retina, choroid and vitreous haemorrhages and vascular disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	3	2.5	5 (3.2)	5	2.3	2 (2.0)	2	1.5
Diabetic retinopathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	2	1.7	3 (1.9)	3	1.4	2 (2.0)	2	1.5
Retinal exudates									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Retinal haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Retinopathy									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Vision disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			4 (2.6)	4	1.9	0		
Amblyopia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Optic nerve disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Presbyopia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Visual acuity reduced									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Ocular infections, irritations and inflammations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	1 (1.0)	1	0.7
Conjunctivitis allergic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Ocular hyperaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Eye disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	2	0.9	1 (1.0)	1	0.7
Lacrimal disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Lacrimation increased									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Dry eye									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Glaucoma and ocular hypertension									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Glaucoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Open angle glaucoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Ocular haemorrhages and vascular disorders NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Optic disc haemorrhage									
>= 20% Weight loss	0			0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Conjunctival haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Ocular structural change, deposit and degeneration NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Retinal tear									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Macular fibrosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Rhegmatogenous retinal detachment									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Reproductive system and breast disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	3 (3.5)	4	3.4	8 (5.2)	9	4.2	0		
Menstrual cycle and uterine bleeding disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			3 (1.9)	3	1.4	0		
Menstruation irregular									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
< 20% Weight loss	0				0				0			
Dysmenorrhoea												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				2	(1.3)	2	0.9	0			
Menstrual disorder												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Prostatic disorders (excl infections and inflammations)												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	2	(1.3)	2	0.9	0			
Benign prostatic hyperplasia												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	2	(1.3)	2	0.9	0			
Breast disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Breast calcifications												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Male reproductive tract infections and inflammations												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	2	0.9	0			
Prostatitis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	2	0.9	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Menopause related conditions									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Menopausal symptoms									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Uterine, pelvic and broad ligament disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	3	2.5	0			0		
Endometrial hyperplasia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Endometriosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Uterine haemorrhage									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Renal and urinary disorders									
>= 20% Weight loss	1 (9.1)	1	6.4	1 (2.6)	1	1.9	0		
< 20% Weight loss	4 (4.7)	5	4.2	4 (2.6)	4	1.9	5 (5.1)	7	5.1
Urolithiases									
>= 20% Weight loss	1 (9.1)	1	6.4	1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	3 (3.1)	5	3.6
Ureterolithiasis									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	2 (2.0)	4	2.9
Calculus urinary									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Renal disorders (excl nephropathies)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			2 (1.3)	2	0.9	1 (1.0)	1	0.7
Azotaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Renal cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Urinary tract signs and symptoms									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	2	1.7	1 (0.6)	1	0.5	0		
Hyperuricosuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Nocturia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Proteinuria									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Nephropathies									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Diabetic nephropathy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Nephropathy toxic									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Ear and labyrinth disorders									
>= 20% Weight loss	2 (18.2)	2	12.7	1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	2 (1.3)	2	0.9	1 (1.0)	1	0.7
Hearing disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Deafness neurosensory									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Deafness									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Inner ear and VIIIth cranial nerve disorders									
>= 20% Weight loss	2 (18.2)	2	12.7	0			0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Vertigo									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Tinnitus									
>= 20% Weight loss	1 (9.1)	1	6.4	0			0		
< 20% Weight loss	0			0			0		
Psychiatric disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	4 (4.7)	4	3.4	6 (3.9)	6	2.8	1 (1.0)	1	0.7
Sleep disorders and disturbances									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	3	2.5	4 (2.6)	4	1.9	0		
Insomnia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	3 (3.5)	3	2.5	4 (2.6)	4	1.9	0		
Depressed mood disorders and disturbances									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Depression									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Mood disorders and disturbances NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	1 (1.0)	1	0.7
Emotional disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Listless									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Adjustment disorders (incl subtypes)									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Adjustment disorder									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Blood and lymphatic system disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Anaemias nonhaemolytic and marrow depression									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Iron deficiency anaemia									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Anaemia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Spleen, lymphatic and reticuloendothelial system disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Lymphadenitis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Congenital, familial and genetic disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Gastrointestinal tract disorders congenital									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Diverticulitis Meckel's									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Skin and subcutaneous tissue disorders congenital									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Birth mark									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Reproductive neoplasms female benign									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
< 20% Weight loss	0			0			0		
Uterine leiomyoma									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	0			0			0		
Gastrointestinal neoplasms benign									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Intraductal papillary mucinous neoplasm									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Hepatobiliary neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Bile duct adenocarcinoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Renal and urinary tract neoplasms malignant and unspecified									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Clear cell renal cell carcinoma									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Respiratory and mediastinal neoplasms malignant and unspecified									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg				Sema 2.4 mg				Placebo			
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(1.0)	1	0.7
Lung neoplasm malignant												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				1	(1.0)	1	0.7
Hepatobiliary disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	5	(3.2)	5	2.3	1	(1.0)	1	0.7
Missing	1	(33.3)	1	86.8	0				0			
Gallbladder disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				3	(1.9)	3	1.4	0			
Missing	1	(33.3)	1	86.8	0				0			
Cholelithiasis												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				2	(1.3)	2	0.9	0			
Gallbladder polyp												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Hyperplastic cholecystopathy												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				0				0			
Missing	1	(33.3)	1	86.8	0				0			
Hepatic and hepatobiliary disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	1	(1.2)	1	0.8	2	(1.3)	2	0.9	1	(1.0)	1	0.7

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
Hepatic cyst									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Hepatic function abnormal									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Alcoholic liver disease									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Hepatic steatosis									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Immune system disorders									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			1 (1.0)	1	0.7
Allergic conditions									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	2 (2.3)	2	1.7	0			1 (1.0)	1	0.7
Seasonal allergy									
>= 20% Weight loss	0			1 (2.6)	1	1.9	0		
< 20% Weight loss	1 (1.2)	1	0.8	0			1 (1.0)	1	0.7
Food allergy									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	0			0		
Cardiac disorders									

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N (%)	E	R	N (%)	E	R	N (%)	E	R
>= 20% Weight loss	0			0			0		
< 20% Weight loss	2 (2.3)	2	1.7	4 (2.6)	4	1.9	3 (3.1)	3	2.2
Cardiac arrhythmias									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	2 (1.3)	2	0.9	2 (2.0)	2	1.5
Tachycardia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		
Ventricular extrasystoles									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	0		
Arrhythmia									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Atrial fibrillation									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			0			1 (1.0)	1	0.7
Cardiac disorders, signs and symptoms NEC									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Palpitations									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	1 (1.2)	1	0.8	1 (0.6)	1	0.5	1 (1.0)	1	0.7
Coronary artery disorders									
>= 20% Weight loss	0			0			0		
< 20% Weight loss	0			1 (0.6)	1	0.5	0		

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
Subjects are considered on-treatment if any dose of trial product has been administered within the prior 49 days.
MedDRA version 23.1

Adverse events by weight loss at week 68, system organ class, high level group term and preferred term - on-treatment - safety analysis set - STEP 6

	Sema 1.7 mg			Sema 2.4 mg			Placebo		
Subjects with events	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
Acute myocardial infarction												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Endocrine disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Thyroid gland disorders												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Hyperthyroidism												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Surgical and medical procedures												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Gastrointestinal therapeutic procedures												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			
Large intestinal polypectomy												
>= 20% Weight loss	0				0				0			
< 20% Weight loss	0				1	(0.6)	1	0.5	0			

Adverse events with onset prior to randomisation are not included.
Sorted in descending order by system organ class, high level group term, and preferred term based on the proportion of subjects experiencing at least one event.
Subjects and exposure: N: Number of subjects, PYE: Patient-years of exposure
Subjects with events: N: Number of subjects experiencing at least one event, %: Percentage of subjects experiencing at least one event, E: Number of events, R: Event rate per 100 patient-years of exposure.
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ウゴーヒ皮下注 0.25mg SD
ウゴーヒ皮下注 0.5mg SD
ウゴーヒ皮下注 1.0mg SD
ウゴーヒ皮下注 1.7mg SD
ウゴーヒ皮下注 2.4mg SD

2.7.5 参考文献

ノボ ノルディスク ファーマ株式会社

2.7.5 参考文献

参考文献は、Module 2.5、Module 2.7.1、Module 2.7.2、Module 2.7.3 及び Module 2.7.4 の参考文献の項にそれぞれ示した。