1.14.2.1.2　治験薬との因果関係が否定できない有害事象［Source: Table 11.3.2.9］

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
Subjects with any AE [b]	91 (22.9)	187 (47.0)	55 (13.6)	223 (55.2)	32 (8.0)	211 (52.8)	146 (18.2)	410 (51.1)
感染症および寄生虫症	3 (0.8)	165 (41.5)	5 (1.2)	183 (45.3)	4 (1.0)	150 (37.5)	8 (1.0)	348 (43.4)
鼻咽頭炎	1 (0.3)	42 (10.6)	1 (0.2)	46 (11.4)	0	36 (9.0)	2 (0.2)	88 (11.0)
上気道感染	1 (0.3)	25 (6.3)	1 (0.2)	47 (11.6)	0	36 (9.0)	2 (0.2)	72 (9.0)
気管支炎	0	20 (5.0)	1 (0.2)	22 (5.4)	1 (0.3)	18 (4.5)	1 (0.1)	42 (5.2)
尿路感染	0	15 (3.8)	0	18 (4.5)	0	13 (3.3)	0	33 (4.1)
副鼻腔炎	0	12 (3.0)	0	19 (4.7)	0	13 (3.3)	0	31 (3.9)
咽頭炎	1 (0.3)	18 (4.5)	0	11 (2.7)	0	19 (4.8)	1 (0.1)	29 (3.6)
ウイルス性気道感染	0	13 (3.3)	1 (0.2)	7 (1.7)	0	7 (1.8)	1 (0.1)	20 (2.5)
インフルエンザ	0	11 (2.8)	0	8 (2.0)	0	3 (0.8)	0	19 (2.4)
急性副鼻腔炎	0	5 (1.3)	0	13 (3.2)	0	9 (2.3)	0	18 (2.2)
気道感染	0	5 (1.3)	0	11 (2.7)	0	8 (2.0)	0	16 (2.0)
肺炎	0	7 (1.8)	0	4 (1.0)	1 (0.3)	3 (0.8)	0	11 (1.4)
喉頭炎	0	5 (1.3)	0	5 (1.2)	0	8 (2.0)	0	10 (1.2)
鼻炎	0	8 (2.0)	0	2 (0.5)	0	8 (2.0)	0	10 (1.2)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
扁桃炎	0	7 (1.8)	0	3 (0.7)	1 (0.3)	5 (1.3)	0	10 (1.2)
ウイルス性上気道感染	0	7 (1.8)	0	3 (0.7)	0	7 (1.8)	0	10 (1.2)
胃腸炎	0	2 (0.5)	0	7 (1.7)	0	3 (0.8)	0	9 (1.1)
膀胱炎	0	3 (0.8)	0	5 (1.2)	0	3 (0.8)	0	8 (1.0)
気管炎	0	5 (1.3)	0	3 (0.7)	0	3 (0.8)	0	8 (1.0)
下気道感染	0	5 (1.3)	0	2 (0.5)	0	5 (1.3)	0	7 (0.9)
口腔カンジダ症	0	3 (0.8)	0	3 (0.7)	0	2 (0.5)	0	6 (0.7)
咽頭扁桃炎	0	1 (0.3)	0	5 (1.2)	0	2 (0.5)	0	6 (0.7)
口腔ヘルペス	0	1 (0.3)	1 (0.2)	3 (0.7)	0	2 (0.5)	1 (0.1)	4 (0.5)
細菌性気管支炎	0	1 (0.3)	0	3 (0.7)	0	1 (0.3)	0	4 (0.5)
蜂巣炎	0	1 (0.3)	0	3 (0.7)	0	1 (0.3)	0	4 (0.5)
結膜炎	0	2 (0.5)	0	2 (0.5)	0	3 (0.8)	0	4 (0.5)
耳感染	0	2 (0.5)	0	2 (0.5)	0	1 (0.3)	0	4 (0.5)
歯肉炎	0	2 (0.5)	0	2 (0.5)	0	1 (0.3)	0	4 (0.5)
歯膿瘍	0	3 (0.8)	0	1 (0.2)	0	1 (0.3)	0	4 (0.5)
気管気管支炎	0	0	0	4 (1.0)	0	0	0	4 (0.5)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
外陰部腟カンジダ症	0	3 (0.8)	0	0	0	1 (0.3)	0	3 (0.4)
慢性副鼻腔炎	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)
真菌感染	0	0	0	2 (0.5)	0	0	0	2 (0.2)
せつ	0	0	0	2 (0.5)	0	0	0	2 (0.2)
消化管感染	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
限局性感染	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
中耳炎	0	0	0	2 (0.5)	0	1 (0.3)	0	2 (0.2)
細菌性気道感染	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)
虫垂炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
体部白癬	0	0	0	1 (0.2)	0	0	0	1 (0.1)
カンジダ感染	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
眼窩蜂巣炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
子宮頚管炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
皮膚糸状菌症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
感染性下痢	0	1 (0.3)	0	0	0	0	0	1 (0.1)
感染性湿疹	0	0	0	1 (0.2)	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
丹毒	0	1 (0.3)	0	0	0	0	0	1 (0.1)
ウイルス性胃炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
ウイルス性胃腸炎	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
ヘリコバクター性胃炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
帯状疱疹	0	1 (0.3)	0	0	0	2 (0.5)	0	1 (0.1)
感染性皮膚潰瘍	0	1 (0.3)	0	0	0	0	0	1 (0.1)
腎感染	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
細菌性下気道感染	0	1 (0.3)	0	0	0	0	0	1 (0.1)
ウイルス性下気道感染	0	0	0	1 (0.2)	0	0	0	1 (0.1)
乳腺炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
急性中耳炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
爪囲炎	0	1 (0.3)	0	0	0	2 (0.5)	0	1 (0.1)
会陰膿瘍	0	0	0	1 (0.2)	0	0	0	1 (0.1)
腹膜炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
扁桃周囲膿瘍	0	0	0	1 (0.2)	0	0	0	1 (0.1)
細菌性咽頭炎	0	1 (0.3)	0	0	1 (0.3)	1 (0.3)	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
毛巣嚢胞	0	0	0	1 (0.2)	0	0	0	1 (0.1)
ウイルス性肺炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
腎盂腎炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
急性腎盂腎炎	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
慢性腎盂腎炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
ブドウ球菌感染	0	0	0	1 (0.2)	0	0	0	1 (0.1)
足部白癬	0	0	0	1 (0.2)	0	0	0	1 (0.1)
膣感染	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
水痘帯状疱疹ウイルス感染	0	0	0	1 (0.2)	0	0	0	1 (0.1)
外陰膣真菌感染	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肛門膿瘍	0	0	0	0	0	1 (0.3)	0	0
ボルデテラ感染	0	0	0	0	0	1 (0.3)	0	0
遊走性紅斑	0	0	0	0	0	1 (0.3)	0	0
歯肉膿瘍	0	0	0	0	0	1 (0.3)	0	0
ヘモフィルス感染	0	0	0	0	0	1 (0.3)	0	0
単純ヘルペス	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
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Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
肺感染	0	0	0	0	0	1 (0.3)	0	0
ムンプス	0	0	0	0	0	1 (0.3)	0	0
爪真菌症	0	0	0	0	0	1 (0.3)	0	0
外耳炎	0	0	0	0	0	3 (0.8)	0	0
マイコプラズマ性肺炎	0	0	0	0	0	1 (0.3)	0	0
歯髄炎	0	0	0	0	0	1 (0.3)	0	0
細菌性副鼻腔炎	0	0	0	0	0	1 (0.3)	0	0
歯感染	0	0	0	0	0	1 (0.3)	0	0
細菌性上気道感染	0	0	0	0	0	1 (0.3)	0	0
ウイルス感染	0	0	0	0	0	1 (0.3)	0	0
ウイルス性咽頭炎	0	0	0	0	0	1 (0.3)	0	0
外陰部腟炎	0	0	0	0	0	1 (0.3)	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	4 (1.0)	0	5 (1.2)	0	2 (0.5)	0	9 (1.1)
基底細胞癌	0	1 (0.3)	0	2 (0.5)	0	0	0	3 (0.4)
脂肪腫	0	0	0	2 (0.5)	0	0	0	2 (0.2)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
子宮頚部癌	0	1 (0.3)	0	0	0	0	0	1 (0.1)
乳管内乳頭腫	0	1 (0.3)	0	0	0	0	0	1 (0.1)
前立腺腺腫	0	1 (0.3)	0	0	0	0	0	1 (0.1)
子宮平滑筋腫	0	0	0	1 (0.2)	0	0	0	1 (0.1)
脂漏性角化症	0	0	0	0	0	1 (0.3)	0	0
子宮癌	0	0	0	0	0	1 (0.3)	0	0
血液およびリンパ系障害	0	4 (1.0)	1 (0.2)	7 (1.7)	1 (0.3)	8 (2.0)	1 (0.1)	11 (1.4)
貧血	0	2 (0.5)	0	3 (0.7)	0	4 (1.0)	0	5 (0.6)
好酸球増加症	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
出血性貧血	0	0	0	1 (0.2)	0	0	0	1 (0.1)
鉄欠乏性貧血	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
白血球増加症	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
リンパ節症	0	0	0	1 (0.2)	0	2 (0.5)	0	1 (0.1)
赤血球増加症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
白血球減少症	0	0	0	0	1 (0.3)	0	0	0

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[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
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Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
System organ class/Preferred term	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
免疫系障害	0	7 (1.8)	1 (0.2)	2 (0.5)	0	7 (1.8)	1 (0.1)	9 (1.1)
季節性アレルギー	0	2 (0.5)	0	1 (0.2)	0	5 (1.3)	0	3 (0.4)
薬物過敏症	0	1 (0.3)	1 (0.2)	0	0	0	1 (0.1)	1 (0.1)
動物アレルギー	0	1 (0.3)	0	0	0	0	0	1 (0.1)
節足動物咬傷アレルギー	0	1 (0.3)	0	0	0	0	0	1 (0.1)
アナフィラキシー反応	0	1 (0.3)	0	0	0	0	0	1 (0.1)
好酸球性多発血管炎性肉芽腫症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
過敏症	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
食物アレルギー	0	0	0	0	0	1 (0.3)	0	0
内分泌障害	0	3 (0.8)	0	5 (1.2)	0	1 (0.3)	0	8 (1.0)
甲状腺機能低下症	0	1 (0.3)	0	4 (1.0)	0	0	0	5 (0.6)
甲状腺腫	0	2 (0.5)	0	1 (0.2)	0	0	0	3 (0.4)
甲状腺障害	0	1 (0.3)	0	0	0	0	0	1 (0.1)
エストロゲン欠乏症	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
代謝および栄養障害	0	11 (2.8)	0	8 (2.0)	0	6 (1.5)	0	19 (2.4)
高コレステロール血症	0	1 (0.3)	0	2 (0.5)	0	0	0	3 (0.4)
痛風	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
高血糖	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
高脂血症	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
脱水	0	1 (0.3)	0	0	0	0	0	1 (0.1)
コントロール不良の糖尿病	0	0	0	1 (0.2)	0	0	0	1 (0.1)
脂質異常症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
食物不耐性	0	0	0	1 (0.2)	0	0	0	1 (0.1)
耐糖能障害	0	1 (0.3)	0	0	0	0	0	1 (0.1)
高トリグリセリド血症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
低カルシウム血症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
低カリウム血症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
食欲亢進	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
2型糖尿病	0	0	0	1 (0.2)	0	0	0	1 (0.1)
高インスリン症	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
血液量減少症	0	0	0	0	0	1 (0.3)	0	0
ビタミンD欠乏	0	0	0	0	0	1 (0.3)	0	0
精神障害	0	9 (2.3)	2 (0.5)	7 (1.7)	0	7 (1.8)	2 (0.2)	16 (2.0)
不安	0	3 (0.8)	2 (0.5)	1 (0.2)	0	2 (0.5)	2 (0.2)	4 (0.5)
うつ病	0	2 (0.5)	0	4 (1.0)	0	1 (0.3)	0	6 (0.7)
不眠症	0	3 (0.8)	0	1 (0.2)	0	3 (0.8)	0	4 (0.5)
感情不安定	0	1 (0.3)	0	0	0	0	0	1 (0.1)
幻覚	0	0	0	1 (0.2)	0	0	0	1 (0.1)
神経過敏	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
睡眠障害	0	0	0	1 (0.2)	0	0	0	1 (0.1)
不安障害	0	0	0	0	0	1 (0.3)	0	0
失見当識	0	0	0	0	0	1 (0.3)	0	0
ストレス	0	0	0	0	0	1 (0.3)	0	0
神経系障害	7 (1.8)	31 (7.8)	6 (1.5)	41 (10.1)	3 (0.8)	38 (9.5)	13 (1.6)	72 (9.0)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
頭痛	5 (1.3)	18 (4.5)	2 (0.5)	29 (7.2)	2 (0.5)	15 (3.8)	7 (0.9)	47 (5.9)
片頭痛	0	2 (0.5)	0	4 (1.0)	0	3 (0.8)	0	6 (0.7)
浮動性めまい	1 (0.3)	2 (0.5)	0	2 (0.5)	2 (0.5)	6 (1.5)	1 (0.1)	4 (0.5)
坐骨神経痛	0	3 (0.8)	0	2 (0.5)	0	1 (0.3)	0	5 (0.6)
失神	0	2 (0.5)	1 (0.2)	1 (0.2)	0	2 (0.5)	1 (0.1)	3 (0.4)
感覚鈍麻	1 (0.3)	0	1 (0.2)	1 (0.2)	0	1 (0.3)	2 (0.2)	1 (0.1)
一過性脳虚血発作	0	3 (0.8)	0	0	0	0	0	3 (0.4)
傾眠	0	0	2 (0.5)	0	0	1 (0.3)	2 (0.2)	0
緊張性頭痛	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
失声症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
頚動脈硬化症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
脳出血	0	0	0	1 (0.2)	0	0	0	1 (0.1)
脳血管障害	0	0	0	1 (0.2)	0	0	0	1 (0.1)
脳軟化	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肋間神経痛	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
虚血性脳卒中	0	1 (0.3)	0	0	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
神経痛	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
錯感覚	0	1 (0.3)	0	0	0	0	0	1 (0.1)
血管性脳症	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
椎骨脳底動脈不全		1 (0.3)	0	0	0	0	0	1 (0.1)
自律神経失調	0	0	0	0	0	1 (0.3)	0	0
手根管症候群	0	0	0	0	0	3 (0.8)	0	0
意識レベルの低下	0	0	0	0	0	1 (0.3)	0	0
出血性卒中	0	0	0	0	0	1 (0.3)	0	0
神経圧迫	0	0	0	0	0	1 (0.3)	0	0
パーキンソン病	0	0	0	0	0	1 (0.3)	0	0
神経根障害	0	0	0	0	0	2 (0.5)	0	0
脊髄ヘルニア	0	0	0	0	0	1 (0.3)	0	0
眼障害	0	10 (2.5)	0	9 (2.2)	0	12 (3.0)	0	19 (2.4)
白内障	0	1 (0.3)	0	3 (0.7)	0	1 (0.3)	0	4 (0.5)
アレルギー性結膜炎	0	2 (0.5)	0	1 (0.2)	0	1 (0.3)	0	3 (0.4)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
眼そう痒症	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
眼瞼浮腫	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)
緑内障	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
結膜刺激	0	1 (0.3)	0	0	0	0	0	1 (0.1)
角膜障害	0	1 (0.3)	0	0	0	0	0	1 (0.1)
複視	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
眼の炎症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
涙腺肥大	0	0	0	1 (0.2)	0	0	0	1 (0.1)
黄斑症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
網膜剥離	0	1 (0.3)	0	0	0	0	0	1 (0.1)
眼瞼炎	0	0	0	0	0	1 (0.3)	0	0
後天性涙道狭窄	0	0	0	0	0	2 (0.5)	0	0
眼乾燥	0	0	0	0	0	2 (0.5)	0	0
角膜炎	0	0	0	0	0	1 (0.3)	0	0
近視	0	0	0	0	0	1 (0.3)	0	0
眼部不快感	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
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Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
翼状片	0	0	0	0	0	1 (0.3)	0	0
斜視	0	0	0	0	0	1 (0.3)	0	0
霧視	0	0	0	0	0	1 (0.3)	0	0
耳および迷路障害	0	2 (0.5)	0	4 (1.0)	0	3 (0.8)	0	6 (0.7)
耳痛	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
回転性めまい	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
伝音難聴	0	0	0	1 (0.2)	0	0	0	1 (0.1)
難聴	0	0	0	1 (0.2)	0	0	0	1 (0.1)
内耳の炎症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
耳鳴	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
耳漏	0	0	0	0	0	1 (0.3)	0	0
前庭障害	0	0	0	0	0	1 (0.3)	0	0
心臓障害	0	11 (2.8)	0	10 (2.5)	1 (0.3)	11 (2.8)	0	21 (2.6)
心房細動	0	3 (0.8)	0	2 (0.5)	0	0	0	5 (0.6)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
狭心症	0	2 (0.5)	0	1 (0.2)	0	2 (0.5)	0	3 (0.4)
頻脈	0	1 (0.3)	0	2 (0.5)	0	1 (0.3)	0	3 (0.4)
心不全	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
動悸	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
急性心筋梗塞	0	1 (0.3)	0	0	0	2 (0.5)	0	1 (0.1)
不安定狭心症	0	1 (0.3)	0	0	0	0	0	1 (0.1)
不整脈	0	1 (0.3)	0	0	0	2 (0.5)	0	1 (0.1)
右脚ブロック	0	1 (0.3)	0	0	0	0	0	1 (0.1)
急性心不全	0	1 (0.3)	0	0	0	0	0	1 (0.1)
うっ血性心不全	0	1 (0.3)	0	0	0	0	0	1 (0.1)
心血管障害	0	0	0	1 (0.2)	0	0	0	1 (0.1)
冠動脈疾患	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
チアノーゼ	0	0	0	1 (0.2)	0	0	0	1 (0.1)
混合性僧帽弁疾患	0	1 (0.3)	0	0	0	0	0	1 (0.1)
心膜炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
洞性徐脈	0	1 (0.3)	0	0	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
洞性頻脈	0	0	0	1 (0.2)	0	0	0	1 (0.1)
上室性頻脈	0	0	0	1 (0.2)	0	0	0	1 (0.1)
発作性頻脈	0	1 (0.3)	0	0	0	0	0	1 (0.1)
徐脈性不整脈	0	0	0	0	0	1 (0.3)	0	0
徐脈	0	0	0	0	1 (0.3)	0	0	0
心筋梗塞	0	0	0	0	0	1 (0.3)	0	0
洞結節機能不全	0	0	0	0	0	1 (0.3)	0	0
心室性期外収縮	0	0	0	0	0	1 (0.3)	0	0
血管障害	3 (0.8)	17 (4.3)	1 (0.2)	15 (3.7)	1 (0.3)	11 (2.8)	4 (0.5)	32 (4.0)
高血圧	1 (0.3)	10 (2.5)	0	12 (3.0)	0	8 (2.0)	1 (0.1)	22 (2.7)
血腫	0	0	0	2 (0.5)	0	0	0	2 (0.2)
末梢静脈疾患	0	2 (0.5)	0	0	0	0	0	2 (0.2)
表在性血栓性静脈炎	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
循環虚脱	1 (0.3)	0	0	0	0	0	1 (0.1)	0
血液溢出	0	1 (0.3)	0	0	0	0	0	1 (0.1)

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[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
ほてり	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
充血	1 (0.3)	0	0	0	0	0	1 (0.1)	0
末梢動脈閉塞性疾患	0	1 (0.3)	0	0	0	0	0	1 (0.1)
静脈瘤破裂	0	0	1 (0.2)	0	0	0	1 (0.1)	0
血管炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
潮紅	0	0	0	0	1 (0.3)	0	0	0
静脈炎	0	0	0	0	0	1 (0.3)	0	0
静脈瘤	0	0	0	0	0	1 (0.3)	0	0
呼吸器、胸郭および縦隔障害	6 (1.5)	95 (23.9)	4 (1.0)	86 (21.3)	3 (0.8)	88 (22.0)	10 (1.2)	181 (22.6)
喘息	2 (0.5)	45 (11.3)	0	48 (11.9)	2 (0.5)	52 (13.0)	2 (0.2)	93 (11.6)
口腔咽頭痛	0	18 (4.5)	0	11 (2.7)	0	3 (0.8)	0	29 (3.6)
咳嗽	0	12 (3.0)	1 (0.2)	12 (3.0)	0	12 (3.0)	1 (0.1)	24 (3.0)
アレルギー性鼻炎	0	10 (2.5)	1 (0.2)	14 (3.5)	0	14 (3.5)	1 (0.1)	24 (3.0)
呼吸困難	0	5 (1.3)	0	9 (2.2)	0	7 (1.8)	0	14 (1.7)
鼻漏	0	1 (0.3)	1 (0.2)	5 (1.2)	0	2 (0.5)	1 (0.1)	6 (0.7)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
湿性咳嗽	0	3 (0.8)	0	2 (0.5)	0	5 (1.3)	0	5 (0.6)
鼻出血	1 (0.3)	1 (0.3)	0	2 (0.5)	0	1 (0.3)	1 (0.1)	3 (0.4)
カタル	0	2 (0.5)	0	1 (0.2)	0	2 (0.5)	0	3 (0.4)
発声障害	0	2 (0.5)	0	1 (0.2)	0	0	0	3 (0.4)
喀痰増加	0	0	0	3 (0.7)	0	1 (0.3)	0	3 (0.4)
喘鳴	1 (0.3)	1 (0.3)	0	1 (0.2)	0	5 (1.3)	1 (0.1)	2 (0.2)
無気肺	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
気管支痙攣	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)
喀血	1 (0.3)	0	0	1 (0.2)	0	0	1 (0.1)	1 (0.1)
鼻閉	0	2 (0.5)	0	0	0	3 (0.8)	0	2 (0.2)
肺塞栓症	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
副鼻腔うっ血	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
くしゃみ	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
咽喉刺激感	1 (0.3)	1 (0.3)	0	0	0	2 (0.5)	1 (0.1)	1 (0.1)
アレルギー性胞隔炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
過換気	0	0	0	1 (0.2)	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
下気道の炎症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
鼻茸	0	1 (0.3)	0	0	0	0	0	1 (0.1)
夜間呼吸困難	0	0	0	1 (0.2)	0	0	0	1 (0.1)
呼吸時疼痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
咽頭浮腫	1 (0.3)	0	0	0	0	0	1 (0.1)	0
胸膜痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
肺うっ血	0	0	0	1 (0.2)	0	0	0	1 (0.1)
副鼻腔痛	0	1 (0.3)	0	0	0	0	0	1 (0.1)
副鼻腔ポリープ	0	1 (0.3)	0	0	0	0	0	1 (0.1)
睡眠時無呼吸症候群	0	0	0	1 (0.2)	0	0	0	1 (0.1)
いびき	0	1 (0.3)	0	0	0	0	0	1 (0.1)
上気道うっ血	0	0	0	1 (0.2)	0	0	0	1 (0.1)
上気道の炎症	0	0	1 (0.2)	0	0	1 (0.3)	1 (0.1)	0
上気道咳症候群	0	1 (0.3)	0	0	0	0	0	1 (0.1)
運動誘発喘息	0	0	0	0	0	1 (0.3)	0	0
発作性夜間呼吸困難	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
高粘稠性気管支分泌物	0	0	0	0	1 (0.3)	0	0	0
咽頭の炎症	0	0	0	0	0	1 (0.3)	0	0
鼻痛	0	0	0	0	0	1 (0.3)	0	0
胃腸障害	2 (0.5)	42 (10.6)	3 (0.7)	43 (10.6)	2 (0.5)	44 (11.0)	5 (0.6)	85 (10.6)
下痢	1 (0.3)	12 (3.0)	0	6 (1.5)	1 (0.3)	8 (2.0)	1 (0.1)	18 (2.2)
胃食道逆流性疾患	0	6 (1.5)	0	6 (1.5)	0	12 (3.0)	0	12 (1.5)
嘔吐	0	5 (1.3)	0	5 (1.2)	0	4 (1.0)	0	10 (1.2)
胃炎	0	5 (1.3)	0	3 (0.7)	0	1 (0.3)	0	8 (1.0)
悪心	0	5 (1.3)	0	3 (0.7)	1 (0.3)	1 (0.3)	0	8 (1.0)
腹痛	0	2 (0.5)	0	5 (1.2)	1 (0.3)	3 (0.8)	0	7 (0.9)
消化不良	0	1 (0.3)	0	6 (1.5)	0	3 (0.8)	0	7 (0.9)
歯痛	0	3 (0.8)	0	2 (0.5)	0	2 (0.5)	0	5 (0.6)
便秘	0	1 (0.3)	0	3 (0.7)	0	2 (0.5)	0	4 (0.5)
腹部膨満	0	1 (0.3)	0	2 (0.5)	1 (0.3)	1 (0.3)	0	3 (0.4)
下腹部痛	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
慢性胃炎	0	1 (0.3)	1 (0.2)	0	0	3 (0.8)	1 (0.1)	1 (0.1)
裂孔ヘルニア	0	1 (0.3)	0	1 (0.2)	0	2 (0.5)	0	2 (0.2)
口唇腫脹	0	0	2 (0.5)	0	0	0	2 (0.2)	0
腹部ヘルニア	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
上腹部痛	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
大腸炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
歯嚢胞	0	1 (0.3)	0	0	0	0	0	1 (0.1)
歯不快感	0	1 (0.3)	0	0	0	0	0	1 (0.1)
横隔膜ヘルニア	0	1 (0.3)	0	0	0	0	0	1 (0.1)
口内乾燥	0	1 (0.3)	0	0	0	0	0	1 (0.1)
小腸炎	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
腸炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
びらん性十二指腸炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
胃ポリープ	0	1 (0.3)	0	0	0	0	0	1 (0.1)
胃潰瘍	0	0	0	1 (0.2)	0	0	0	1 (0.1)
びらん性胃炎	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
胃十二指腸炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
歯肉出血	0	0	0	1 (0.2)	0	0	0	1 (0.1)
痔核	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
過敏性腸症候群	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
嚥下痛	0	1 (0.3)	0	0	0	0	0	1 (0.1)
口腔内不快感	0	1 (0.3)	0	0	0	0	0	1 (0.1)
慢性膵炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
歯周病	0	1 (0.3)	0	0	0	0	0	1 (0.1)
唾液腺障害	0	0	0	1 (0.2)	0	0	0	1 (0.1)
口内炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
舌腫脹	1 (0.3)	0	0	0	0	0	1 (0.1)	0
アフタ性潰瘍	0	0	0	0	0	1 (0.3)	0	0
潰瘍性大腸炎	0	0	0	0	0	1 (0.3)	0	0
齲歯	0	0	0	0	0	2 (0.5)	0	0
胃腸出血	0	0	0	0	0	1 (0.3)	0	0
血便排泄	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
System organ class/Preferred term	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
口腔粘膜剥脱	0	0	0	0	1 (0.3)	0	0	0
口腔そう痒症	0	0	0	0	0	1 (0.3)	0	0
直腸出血	0	0	0	0	0	1 (0.3)	0	0
臍ヘルニア	0	0	0	0	0	1 (0.3)	0	0
肝胆道系障害	0	4 (1.0)	0	5 (1.2)	0	3 (0.8)	0	9 (1.1)
胆石症	0	2 (0.5)	0	1 (0.2)	0	1 (0.3)	0	3 (0.4)
脂肪肝	0	0	0	2 (0.5)	0	1 (0.3)	0	2 (0.2)
胆道仙痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
胆道ジスキネジア	0	0	0	1 (0.2)	0	0	0	1 (0.1)
急性胆嚢炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
慢性胆嚢炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
肝機能異常	0	1 (0.3)	0	0	0	0	0	1 (0.1)
中毒性肝炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肝嚢胞	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
皮膚および皮下組織障害	8 (2.0)	19 (4.8)	4 (1.0)	21 (5.2)	7 (1.8)	18 (4.5)	12 (1.5)	40 (5.0)
発疹	1 (0.3)	7 (1.8)	0	4 (1.0)	2 (0.5)	3 (0.8)	1 (0.1)	11 (1.4)
そう痒症	3 (0.8)	2 (0.5)	1 (0.2)	2 (0.5)	2 (0.5)	1 (0.3)	4 (0.5)	4 (0.5)
蕁麻疹	0	3 (0.8)	1 (0.2)	3 (0.7)	1 (0.3)	3 (0.8)	1 (0.1)	6 (0.7)
紅斑	5 (1.3)	0	0	1 (0.2)	0	0	5 (0.6)	1 (0.1)
接触皮膚炎	0	1 (0.3)	0	3 (0.7)	0	0	0	4 (0.5)
乾癬	0	2 (0.5)	0	1 (0.2)	0	1 (0.3)	0	3 (0.4)
脱毛症	0	0	0	2 (0.5)	0	1 (0.3)	0	2 (0.2)
皮膚炎	0	2 (0.5)	0	0	0	0	0	2 (0.2)
湿疹	0	2 (0.5)	0	0	0	4 (1.0)	0	2 (0.2)
皮膚肉芽腫	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
全身性そう痒症	0	1 (0.3)	1 (0.2)	0	0	0	1 (0.1)	1 (0.1)
脂漏性皮膚炎	0	0	0	2 (0.5)	0	0	0	2 (0.2)
血管浮腫	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
アレルギー性皮膚炎	0	0	0	1 (0.2)	0	2 (0.5)	0	1 (0.1)
アトピー性皮膚炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
多汗症	1 (0.3)	0	0	0	0	0	1 (0.1)	0
脂肪織炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
光線過敏性反応	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
痒疹	0	1 (0.3)	0	0	0	0	0	1 (0.1)
全身性皮疹	1 (0.3)	0	0	0	0	0	1 (0.1)	0
斑状丘疹状皮疹	0	1 (0.3)	0	0	0	0	0	1 (0.1)
そう痒性皮疹	1 (0.3)	0	0	0	0	0	1 (0.1)	0
日光皮膚炎	0	0	1 (0.2)	0	0	0	1 (0.1)	0
皮膚嚢腫	0	0	0	0	0	1 (0.3)	0	0
アレルギー性そう痒症	0	0	0	0	1 (0.3)	0	0	0
紅斑性皮疹	0	0	0	0	0	1 (0.3)	0	0
皮膚病変	0	0	0	0	1 (0.3)	0	0	0
慢性蕁麻疹	0	0	0	0	0	1 (0.3)	0	0
筋骨格系および結合組織障害	4 (1.0)	47 (11.8)	3 (0.7)	42 (10.4)	1 (0.3)	51 (12.8)	7 (0.9)	89 (11.1)
背部痛	0	11 (2.8)	0	14 (3.5)	0	13 (3.3)	0	25 (3.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
関節痛	0	12 (3.0)	0	11 (2.7)	0	11 (2.8)	0	23 (2.9)
筋肉痛	1 (0.3)	3 (0.8)	3 (0.7)	2 (0.5)	1 (0.3)	0	4 (0.5)	5 (0.6)
四肢痛	1 (0.3)	2 (0.5)	0	6 (1.5)	0	3 (0.8)	1 (0.1)	8 (1.0)
筋痙縮	1 (0.3)	4 (1.0)	0	3 (0.7)	0	3 (0.8)	1 (0.1)	7 (0.9)
頚部痛	0	4 (1.0)	0	2 (0.5)	0	0	0	6 (0.7)
腱炎	0	3 (0.8)	0	2 (0.5)	0	1 (0.3)	0	5 (0.6)
筋骨格系胸痛	0	1 (0.3)	0	3 (0.7)	0	0	0	4 (0.5)
筋骨格痛	1 (0.3)	2 (0.5)	0	1 (0.2)	0	5 (1.3)	1 (0.1)	3 (0.4)
骨粗鬆症	0	4 (1.0)	0	0	0	2 (0.5)	0	4 (0.5)
脊椎痛	0	2 (0.5)	0	2 (0.5)	0	1 (0.3)	0	4 (0.5)
椎間板障害	0	2 (0.5)	0	1 (0.2)	0	1 (0.3)	0	3 (0.4)
変形性関節症	0	1 (0.3)	0	2 (0.5)	0	7 (1.8)	0	3 (0.4)
変形性脊椎症	0	2 (0.5)	0	1 (0.2)	0	2 (0.5)	0	3 (0.4)
骨痛	0	0	1 (0.2)	1 (0.2)	0	0	1 (0.1)	1 (0.1)
軟骨炎	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
関節腫脹	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
筋骨格硬直	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
骨端症	0	0	0	2 (0.5)	0	0	0	2 (0.2)
強直性脊椎炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
関節炎	0	1 (0.3)	0	0	0	3 (0.8)	0	1 (0.1)
反応性関節炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
滑液包炎	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
肋軟骨炎	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
外骨腫	0	0	0	1 (0.2)	0	0	0	1 (0.1)
側腹部痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
椎間板突出	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
骨壊死	0	1 (0.3)	0	0	0	0	0	1 (0.1)
骨減少症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
関節周囲炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
末梢関節炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肩回旋筋腱板症候群	0	1 (0.3)	0	0	0	2 (0.5)	0	1 (0.1)
軟部組織腫脹	0	1 (0.3)	0	0	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
滑膜炎	0	0	0	1 (0.2)	0	0	0	1 (0.1)
線維筋痛	0	0	0	0	0	1 (0.3)	0	0
肩径部痛	0	0	0	0	0	1 (0.3)	0	0
関節可動域低下	0	0	0	0	0	1 (0.3)	0	0
筋力低下	0	0	0	0	0	1 (0.3)	0	0
骨炎	0	0	0	0	0	1 (0.3)	0	0
関節リウマチ	0	0	0	0	0	1 (0.3)	0	0
狭窄性腱鞘炎	0	0	0	0	0	1 (0.3)	0	0
弾発指	0	0	0	0	0	2 (0.5)	0	0
腎および尿路障害	0	4 (1.0)	0	7 (1.7)	0	5 (1.3)	0	11 (1.4)
血尿	0	2 (0.5)	0	1 (0.2)	0	1 (0.3)	0	3 (0.4)
排尿困難	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
腎結石症	0	0	0	2 (0.5)	0	0	0	2 (0.2)
腎臓痛	0	0	0	2 (0.5)	0	0	0	2 (0.2)
非感染性膀胱炎	0	1 (0.3)	0	0	0	0	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
ケトン尿	0	1 (0.3)	0	0	0	0	0	1 (0.1)
蛋白尿	0	1 (0.3)	0	0	0	0	0	1 (0.1)
腎仙痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
腎嚢胞	0	0	0	1 (0.2)	0	2 (0.5)	0	1 (0.1)
頻尿	0	0	0	0	0	1 (0.3)	0	0
尿管結石症	0	0	0	0	0	1 (0.3)	0	0
生殖系および乳房障害	1 (0.3)	7 (1.8)	0	11 (2.7)	0	2 (0.5)	1 (0.1)	18 (2.2)
卵巣嚢胞	0	0	0	2 (0.5)	0	0	0	2 (0.2)
前立腺炎	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
子宮付属器腫瘤	0	0	0	1 (0.2)	0	0	0	1 (0.1)
良性前立腺肥大症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
乳房嚢胞	0	1 (0.3)	0	0	0	0	0	1 (0.1)
乳房過形成	0	0	0	1 (0.2)	0	0	0	1 (0.1)
乳房腫瘤	0	0	0	1 (0.2)	0	0	0	1 (0.1)
乳房浮腫	1 (0.3)	0	0	0	0	0	1 (0.1)	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
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Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
乳房痛	0	1 (0.3)	0	0	0	0	0	1 (0.1)
乳房腫脹	1 (0.3)	0	0	0	0	0	1 (0.1)	0
子宮頚部上皮異形成	0	0	0	1 (0.2)	0	0	0	1 (0.1)
月経困難症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
性器出血	0	1 (0.3)	0	0	0	0	0	1 (0.1)
過少月経	0	1 (0.3)	0	0	0	0	0	1 (0.1)
不正子宮出血	0	1 (0.3)	0	0	0	0	0	1 (0.1)
頻発月経	0	1 (0.3)	0	0	0	0	0	1 (0.1)
前立腺腫大	0	1 (0.3)	0	0	0	0	0	1 (0.1)
腟出血	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
外陰白斑病	0	0	0	1 (0.2)	0	0	0	1 (0.1)
一般・全身障害および投与部位の状態	70 (17.6)	18 (4.5)	42 (10.4)	17 (4.2)	13 (3.3)	13 (3.3)	112 (14.0)	35 (4.4)
注射部位紅斑	23 (5.8)	1 (0.3)	12 (3.0)	0	0	0	35 (4.4)	1 (0.1)
注射部位反応	15 (3.8)	1 (0.3)	13 (3.2)	0	0	0	28 (3.5)	1 (0.1)
注射部位疼痛	15 (3.8)	0	10 (2.5)	0	10 (2.5)	1 (0.3)	25 (3.1)	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
注射部位そう痒感	13 (3.3)	1 (0.3)	7 (1.7)	0	0	0	20 (2.5)	1 (0.1)
注射部位腫脹	6 (1.5)	1 (0.3)	4 (1.0)	0	0	0	10 (1.2)	1 (0.1)
疲労	2 (0.5)	3 (0.8)	2 (0.5)	3 (0.7)	0	2 (0.5)	4 (0.5)	6 (0.7)
発熱	1 (0.3)	4 (1.0)	2 (0.5)	3 (0.7)	0	3 (0.8)	3 (0.4)	7 (0.9)
注射部位過敏反応	4 (1.0)	1 (0.3)	4 (1.0)	0	0	0	8 (1.0)	1 (0.1)
注射部位内出血	3 (0.8)	1 (0.3)	2 (0.5)	1 (0.2)	0	0	5 (0.6)	2 (0.2)
投与部位反応	4 (1.0)	1 (0.3)	0	0	0	0	4 (0.5)	1 (0.1)
無力症	0	2 (0.5)	0	3 (0.7)	1 (0.3)	2 (0.5)	0	5 (0.6)
注射部位発疹	4 (1.0)	0	1 (0.2)	0	0	0	5 (0.6)	0
非心臓性胸痛	0	1 (0.3)	0	4 (1.0)	0	0	0	5 (0.6)
注射部位蕁麻疹	3 (0.8)	0	1 (0.2)	0	1 (0.3)	0	4 (0.5)	0
投与部位紅斑	1 (0.3)	1 (0.3)	1 (0.2)	0	0	0	2 (0.2)	1 (0.1)
注射部位浮腫	1 (0.3)	2 (0.5)	0	0	0	0	1 (0.1)	2 (0.2)
末梢性浮腫	1 (0.3)	1 (0.3)	0	1 (0.2)	0	2 (0.5)	1 (0.1)	2 (0.2)
インフルエンザ様疾患	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
注射部位漏出	2 (0.5)	0	0	0	0	0	2 (0.2)	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
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Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
注射部位血腫	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
注射部位丘疹	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)	0
倦怠感	0	2 (0.5)	0	0	0	1 (0.3)	0	2 (0.2)
投与部位不快感	0	0	1 (0.2)	0	0	0	1 (0.1)	0
投与部位腫脹	0	0	1 (0.2)	0	0	0	1 (0.1)	0
適用部位紅斑	0	0	0	1 (0.2)	0	0	0	1 (0.1)
適用部位過敏反応	0	0	1 (0.2)	0	0	0	1 (0.1)	0
適用部位炎症	1 (0.3)	0	0	0	0	0	1 (0.1)	0
溺死	0	1 (0.3)	0	0	0	0	0	1 (0.1)
運動耐性低下	0	0	0	1 (0.2)	0	0	0	1 (0.1)
全身健康状態低下	0	1 (0.3)	0	0	0	0	0	1 (0.1)
ヘルニア痛	0	0	0	1 (0.2)	0	0	0	1 (0.1)
注射部位変色	1 (0.3)	0	0	0	0	0	1 (0.1)	0
注射部位不快感	0	0	1 (0.2)	0	0	0	1 (0.1)	0
注射部位出血	1 (0.3)	0	0	0	0	1 (0.3)	1 (0.1)	0
注射部位硬結	0	0	1 (0.2)	0	0	0	1 (0.1)	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
注射部位刺激感	1 (0.3)	0	0	0	0	0	1 (0.1)	0
注射部位知覚異常	0	0	0	1 (0.2)	0	0	0	1 (0.1)
末梢腫脹	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
投与部位内出血	0	0	0	0	1 (0.3)	0	0	0
投与部位疼痛	0	0	0	0	1 (0.3)	0	0	0
適用部位疼痛	0	0	0	0	1 (0.3)	0	0	0
全身性浮腫	0	0	0	0	0	1 (0.3)	0	0
臨床検査	2 (0.5)	12 (3.0)	1 (0.2)	15 (3.7)	2 (0.5)	13 (3.3)	3 (0.4)	27 (3.4)
血圧上昇	0	3 (0.8)	0	4 (1.0)	0	3 (0.8)	0	7 (0.9)
γ－グルタミルトランスフェラーゼ増加	1 (0.3)	1 (0.3)	0	5 (1.2)	0	1 (0.3)	1 (0.1)	6 (0.7)
アラニンアミノトランスフェラーゼ増加	0	1 (0.3)	0	5 (1.2)	0	1 (0.3)	0	6 (0.7)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.3)	0	3 (0.7)	0	0	0	4 (0.5)
血中ブドウ糖増加	0	2 (0.5)	0	2 (0.5)	0	1 (0.3)	0	4 (0.5)
血中アルカリホスファターゼ増加	0	0	0	1 (0.2)	0	0	0	1 (0.1)
血中クレアチンホスホキナーゼ増加	0	0	0	1 (0.2)	0	3 (0.8)	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
血中免疫グロブリンE増加	0	0	0	1 (0.2)	0	0	0	1 (0.1)
血中カリウム減少	0	0	0	1 (0.2)	0	0	0	1 (0.1)
血中甲状腺刺激ホルモン増加	0	0	0	1 (0.2)	0	0	0	1 (0.1)
体温上昇	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
心雑音	0	1 (0.3)	0	0	0	0	0	1 (0.1)
好酸球数増加	1 (0.3)	0	0	0	0	0	1 (0.1)	0
ヘモグロビン減少	0	1 (0.3)	0	0	0	0	0	1 (0.1)
心拍数増加	0	0	1 (0.2)	0	0	0	1 (0.1)	0
肝機能検査異常	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肝機能検査値上昇	0	1 (0.3)	0	0	0	0	0	1 (0.1)
好中球数増加	0	1 (0.3)	0	0	0	0	0	1 (0.1)
前立腺特異性抗原増加	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
体重増加	0	1 (0.3)	0	0	0	0	0	1 (0.1)
白血球数増加	0	1 (0.3)	0	0	0	0	0	1 (0.1)
血圧低下	0	0	0	0	1 (0.3)	0	0	0
心電図異常	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
糸球体濾過率減少	0	0	0	0	0	1 (0.3)	0	0
尿中ブドウ糖陽性	0	0	0	0	0	1 (0.3)	0	0
血液学的検査異常	0	0	0	0	0	1 (0.3)	0	0
肝酵素上昇	0	0	0	0	1 (0.3)	0	0	0
傷害、中毒および処置合併症	1 (0.3)	19 (4.8)	0	22 (5.4)	0	26 (6.5)	1 (0.1)	41 (5.1)
骨挫傷	0	2 (0.5)	0	2 (0.5)	0	0	0	4 (0.5)
靭帯捻挫	0	3 (0.8)	0	1 (0.2)	0	2 (0.5)	0	4 (0.5)
四肢損傷	0	3 (0.8)	0	1 (0.2)	0	3 (0.8)	0	4 (0.5)
挫傷	0	3 (0.8)	0	0	0	5 (1.3)	0	3 (0.4)
関節脱臼	0	2 (0.5)	0	1 (0.2)	0	0	0	3 (0.4)
動物咬傷	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
胸部損傷	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
転倒	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)
大腿骨骨折	0	1 (0.3)	0	1 (0.2)	0	0	0	2 (0.2)
足骨折	0	1 (0.3)	0	1 (0.2)	0	1 (0.3)	0	2 (0.2)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
上腕骨骨折	0	2 (0.5)	0	0	0	0	0	2 (0.2)
皮膚損傷	0	0	0	2 (0.5)	0	0	0	2 (0.2)
熱傷	0	0	0	2 (0.5)	0	0	0	2 (0.2)
眼外傷	0	0	0	1 (0.2)	0	0	0	1 (0.1)
眼内異物	0	0	0	1 (0.2)	0	0	0	1 (0.1)
頭部損傷	0	0	0	1 (0.2)	0	0	0	1 (0.1)
関節損傷	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
裂傷	0	1 (0.3)	0	0	0	1 (0.3)	0	1 (0.1)
半月板損傷	0	1 (0.3)	0	0	0	0	0	1 (0.1)
筋損傷	0	0	0	1 (0.2)	0	0	0	1 (0.1)
処置後合併症	0	0	0	1 (0.2)	0	0	0	1 (0.1)
外傷後頚部症候群	0	1 (0.3)	0	0	0	0	0	1 (0.1)
処置による頭痛	0	1 (0.3)	0	0	0	0	0	1 (0.1)
処置による疼痛	0	1 (0.3)	0	0	0	0	0	1 (0.1)
肋骨骨折	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)
交通事故	0	0	0	1 (0.2)	0	1 (0.3)	0	1 (0.1)

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
The 'dosing frequency' equals 2 or 4 weeks depending on whether subjects were randomised to the Q2W or Q4W dosing regimen.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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Table 11.3.2.9 Adverse events reported during the treatment period, by System Organ Class, preferred term and investigator's causality assessment (Safety analysis set)

System organ class/Preferred term	Number (%) of subjects [a]							
	Tralo 300 mg Q2W (N=398) Assessed causality		Tralo 300 mg Q4W (N=404) Assessed causality		Placebo (N=400) Assessed causality		Total Tralo (N=802) Assessed causality	
	Related	Not Related	Related	Not Related	Related	Not Related	Related	Not Related
皮膚創傷	1 (0.3)	0	0	0	0	0	1 (0.1)	0
刺創	0	0	0	1 (0.2)	0	0	0	1 (0.1)
動物による引っかき傷	0	0	0	0	0	1 (0.3)	0	0
足関節部骨折	0	0	0	0	0	1 (0.3)	0	0
背部損傷	0	0	0	0	0	1 (0.3)	0	0
軟骨損傷	0	0	0	0	0	1 (0.3)	0	0
顔面骨骨折	0	0	0	0	0	2 (0.5)	0	0
涙器損傷	0	0	0	0	0	1 (0.3)	0	0
肉離れ	0	0	0	0	0	1 (0.3)	0	0
外傷後疼痛	0	0	0	0	0	2 (0.5)	0	0
処置合併症	0	0	0	0	0	1 (0.3)	0	0
橈骨神経損傷	0	0	0	0	0	1 (0.3)	0	0
皮膚擦過傷	0	0	0	0	0	2 (0.5)	0	0
皮下血腫	0	0	0	0	0	1 (0.3)	0	0
上肢骨折	0	0	0	0	0	1 (0.3)	0	0
創傷	0	0	0	0	0	1 (0.3)	0	0

Sorted for System Organ Class (SOC) by international order and for preferred term (PT) by decreasing frequency in subjects treated with Tralo.
[a] Each subject is represented by the maximum reported causality for each SOC and PT.
[b] Each subject is counted only once within a treatment group in this overall summary.
Includes adverse events with an onset date >= the first day of study treatment and <= (the last day of study treatment + dosing frequency).
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Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.
Subjects with missing causality have been set to related.

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1.14.2.2　死亡および重篤な有害事象

死亡および重篤な有害事象［Source: Table 11.3.3.2.1 および Table 11.3.4.2.1］

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Table 11.3.3.2.1 Adverse Events with outcome of death - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W									
Subject identifier [a]	Sex/ Age (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to death (days)	Time from first dose to death (days)	Received treatment for AE	Reasonable possibility AE causally related to Tralokinumab [b]
[redacted]	F/60	感染性下痢	感染性下痢	31	Treatment	3	37	Yes	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.3.2.1 Adverse Events with outcome of death - key subject information (Safety analysis set)

Group = Tralo 300 mg Q4W									
Subject identifier [a]	Sex/ Age (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to death (days)	Time from first dose to death (days)	Received treatment for AE	Reasonable possibility AE causally related to Tralokinumab [b]
[redacted]	F/54	急性喘息増悪	喘息	204	Treatment	7	228	Yes	No
		脳血管病変	脳血管障害	204	Treatment	7	228	No	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.3.2.1 Adverse Events with outcome of death - key subject information (Safety analysis set)

Group = Placebo

Subject identifier [a]	Sex/ Age (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to death (days)	Time from first dose to death (days)	Received treatment for AE	Reasonable possibility AE causally related to Tralokinumab [b]

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	48	一過性脳虚血発作	一過性脳虚血発作	90	Treatment	6	90	RECOVERED/ RESOLVED WITH SEQUELAE	DOSE NOT CHANGED	No
[redacted]	F	44	胆石	胆石症	162	Post-treatment	28	162	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
[redacted]	F	59	上腕骨骨折	上腕骨骨折	37	Treatment	9	45	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	12	左無気肺	無気肺	2	Treatment	2	2	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
[redacted]	M	49	喘息増悪	喘息	153	Treatment	13	154	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	49	喘息増悪	喘息	240	Treatment	2	241	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	68	腎盂腎炎増悪	腎盂腎炎	44	Treatment	1	71	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			丹毒	丹毒	107	Treatment	10	113	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	177	Treatment	10	177	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
			心膜炎	心膜炎	205	Treatment	9	205	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	68	うっ血性心不全の悪化	うっ血性心不全	242	Treatment	6	244	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	69	虚血性脳卒中	虚血性脳卒中	250	Treatment	12	251	RECOVERED/ RESOLVED WITH SEQUELAE	DRUG WITHDRAWN	No
[redacted]	F	66	十二指腸のびらん	びらん性十二指腸炎	308	Treatment	12	308	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	63	喘息増悪	喘息	60	Treatment	3	60	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	55	喘息増悪	喘息	347	Post-treatment	52	350	RECOVERED/ RESOLVED	NA	No

[a] Age at study entry
[b] As assessed by the investigator.NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	56	喘息増悪	喘息	110	Treatment	15	110	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	M	55	ST上昇を伴う心筋梗塞	急性心筋梗塞	85	Treatment	14	85	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			不安定狭心症	不安定狭心症	89	Treatment	18	89	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
			不安定狭心症	不安定狭心症	187	Treatment	5	187	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	46	喘息増悪	喘息	107	Treatment	12	109	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Group = Tralo 300 mg Q2W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	46	喘息増悪	喘息	344	Treatment	8	344	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	51	左膝内側半月板断裂	半月板損傷	132	Treatment	6	132	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	64	網膜剥離	網膜剥離	271	Treatment	3	271	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	46	不正子宮出血	不正子宮出血	45	Treatment	3	64	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	69	喘息増悪	喘息	11	Treatment	11	12	RECOVERED/ RESOLVED	DRUG INTERRU-PTED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Group = Tralo 300 mg Q2W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	69	血圧上昇	血圧上昇	89	Treatment	6	89	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	263	Treatment	13	263	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			浮動性めまいの悪化	浮動性めまい	273	Treatment	23	273	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			椎骨脳底動脈不全	椎骨脳底動脈不全	288	Treatment	38	288	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	66	喘息増悪	喘息	153	Post-treatment	107	153	RECOVERED/ RESOLVED	NA	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q2W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	66	喘息増悪	喘息	203	Post-treatment	157	203	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			肺炎	肺炎	203	Post-treatment	157	203	RECOVERED/ RESOLVED	NA	No
[redacted]	F	57	一過性脳虚血発作	一過性脳虚血発作	183	Treatment	2	183	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	41	気管支肺炎	肺炎	146	Post-treatment	17	146	RECOVERING/ RESOLVING	NA	No
[redacted]	F	61	肺炎	肺炎	313	Treatment	6	314	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Group = Tralo 300 mg Q2W										
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	63	収縮機能が保持された心不全	心不全	69	Treatment	13	99	NOT RECOVERED/ NOT RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	44	胆嚢結石	胆石症	279	Treatment	1	279	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	60	感染性下痢	感染性下痢	31	Treatment	3	35	FATAL	DRUG WITHDRAWN	No
[redacted]	M	53	コンクリート板上の転倒	転倒	130	Treatment	5	130	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			転倒による左大腿骨転子部骨折	大腿骨骨折	130	Treatment	5	130	RECOVERING/ RESOLVING	DRUG INTERRUPTED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.

Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
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Group = Tralo 300 mg Q2W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	53	左上腕骨大結節骨折	上腕骨骨折	130	Treatment	5	130	RECOVERING/ RESOLVING	DRUG INTERRUPTED	No
			左肩脱臼	関節脱臼	130	Treatment	5	130	RECOVERING/ RESOLVING	DRUG INTERRUPTED	No
[redacted]	F	42	貧血の悪化	貧血	14	Treatment	14	34	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	66	冠動脈疾患の悪化および入院	冠動脈疾患	85	Treatment	3	85	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	52	卵巣癌	卵巣癌	163	Post-treatment	23	163	RECOVERING/ RESOLVING	DRUG WITHDRAWN	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.

Time from last dose to AE is the time from the dose prior to the AE start date.
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Group = Tralo 300 mg Q2W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	50	虫垂炎	虫垂炎	318	Treatment	11	318	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	63	子宮頚部癌	子宮頚部癌	67	Treatment	13	67	RECOVERING/ RESOLVING	DRUG WITHDRAWN	No
[redacted]	M	49	喘息増悪	喘息	199	Treatment	2	199	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	46	腰椎変性による発痛性症候群の悪化	脊椎痛	34	Treatment	9	34	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	31	抑うつ	うつ病	231	Treatment	7	231	NOT RECOVERED/ NOT RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	51	喘息増悪	喘息	47	Treatment	5	47	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	66	のどの腫れ	咽頭浮腫	1	Treatment	1	1	RECOVERED/ RESOLVED	DRUG WITHDRAWN	Yes
			舌の腫れ	舌腫脹	1	Treatment	1	1	RECOVERED/ RESOLVED	DRUG WITHDRAWN	Yes
[redacted]	M	49	急性胆嚢炎による疼痛	急性胆嚢炎	25	Treatment	11	25	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			胆石症	胆石症	25	Treatment	11	25	RECOVERED/ RESOLVED WITH SEQUELAE	DOSE NOT CHANGED	No

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[b] As assessed by the investigator.
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Time from last dose to AE is the time from the dose prior to the AE start date.
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	49	急性胆嚢炎	急性胆嚢炎	281	Treatment	15	281	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	M	61	肺炎	肺炎	179	Treatment	11	179	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			他に分類される疾患における右下葉の肺炎	肺炎	260	Treatment	8	260	RECOVERING/ RESOLVING	NA	No
[redacted]	M	34	喘息増悪	喘息	-73	Pre-treatment		-73	RECOVERED/ RESOLVED	NA	No
[redacted]	F	74	喘息の急性増悪	喘息	13	Treatment	1	13	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	74	発作性心房細動の悪化	心房細動	13	Treatment	1	13	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			急性うっ血性心不全	急性心不全	13	Treatment	1	13	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			脂質異常症の悪化	脂質異常症	13	Treatment	1	13	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	65	喘息増悪	喘息	76	Treatment	5	76	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	F	62	低カリウム血症	低カリウム血症	309	Treatment	18	309	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	37	肺炎	肺炎	270	Treatment	9	270	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
			肺塞栓症	肺塞栓症	270	Treatment	9	270	RECOVERED/ RESOLVED WITH SEQUELAE	DRUG WITHDRAWN	No
			肺炎	肺炎	316	Post-treatment	55	316	RECOVERED/ RESOLVED	NA	No
[redacted]	M	46	喘息増悪	喘息	213	Treatment	16	213	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	13	血管浮腫	血管浮腫	292	Treatment	13	292	RECOVERING/ RESOLVING	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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[redacted]	F	67	浸潤性基底細胞癌	基底細胞癌	164	Treatment	10	180	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
[redacted]	M	41	喘息増悪	喘息	16	Treatment	16	16	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q4W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	51	喘息増悪	喘息	108	Treatment	24	108	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	54	急性喘息増悪	喘息	204	Treatment	7	204	FATAL	DRUG WITHDRAWN	No
			脳血管病変	脳血管障害	204	Treatment	7	212	FATAL	DRUG WITHDRAWN	No
[redacted]	F	61	喘息増悪	喘息	191	Treatment	21	191	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	45	ステロイドの全身投与により治療した喘息増悪	喘息	52	Treatment	24	52	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q4W											
Subject identi-tifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investi-gational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	45	喘息増悪	喘息	299	Treatment	19	299	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	68	ウイルス性肺炎	ウイルス性肺炎	144	Treatment	1	145	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	36	喘息増悪	喘息	38	Treatment	10	38	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	46	喘息増悪	喘息	100	Treatment	16	100	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	50	喘息増悪	喘息	5	Treatment	5	5	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q4W

Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	53	両側性肺炎	肺炎	242	Treatment	18	246	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	59	喘息増悪	喘息	99	Treatment	15	100	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	253	Treatment	1	253	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	52	喘息増悪	喘息	323	Treatment	16	323	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	73	喘息増悪	喘息	319	Treatment	11	319	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
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PSC1
Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Tralo 300 mg Q4W											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	54	強直性脊椎炎の悪化	強直性脊椎炎	214	Treatment	19	214	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	69	大腿骨骨折	大腿骨骨折	233	Treatment	9	233	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	F	72	老人性白内障の悪化	白内障	78	Treatment	22	78	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			老人性白内障の悪化(右側)	白内障	134	Treatment	50	134	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			変形性膝関節症の悪化	変形性関節症	238	Treatment	19	238	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
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[redacted]	F	52	卵巣嚢胞	卵巣嚢胞	41	Treatment	11	41	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	56	白内障	白内障	110	Treatment	1	110	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	34	喘息	喘息	327	Treatment	19	327	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	53	呼吸器科への入院に至った喘息増悪	喘息	-70	Pre-treatment		-70	RECOVERED/ RESOLVED	NA	No
			喘息増悪	喘息	133	Treatment	21	133	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	M	66	医学的な異常の理由を特定できなかったCK上昇	血中クレアチンホスホキナーゼ増加	1	Pre-treatment	1	23	RECOVERING/ RESOLVING	DRUG INTERRUPTED	No
			喘息増悪	喘息	89	Post-treatment	33	89	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
			胆石症	胆石症	112	Post-treatment	56	112	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
			眼白内障	白内障	165	Post-treatment	109	165	RECOVERED/ RESOLVED	NA	No
[redacted]	M	38	慢性幻覚の増悪	幻覚	69	Treatment	12	69	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
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[redacted]	M	38	感染性喘息の増悪	喘息	333	Post-treatment	81	352	RECOVERED/ RESOLVED	NA	No
[redacted]	F	39	両側性胸膜肺炎	肺炎	132	Treatment	23	132	RECOVERED/ RESOLVED	NA	No
			両側性胸膜肺炎後の診断	肺炎	166	Post-treatment	57	166	RECOVERED/ RESOLVED	NA	No
			両側性胸膜肺炎後の診断	肺炎	203	Post-treatment	94	203	RECOVERED/ RESOLVED	NA	No
[redacted]	F	65	喘息増悪	喘息	164	Treatment	27	164	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

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[redacted]	F	63	発作性上室性頻拍	上室性頻脈	66	Treatment	7	66	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	55	臍ヘルニア	臍ヘルニア	273	Post-treatment	52	273	RECOVERED/ RESOLVED	NA	No
[redacted]	M	71	右側肺炎	肺炎	53	Treatment	25	53	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	F	63	脳出血	脳出血	124	Treatment	12	124	RECOVERING/ RESOLVING	NA	No
			高血圧の悪化	高血圧	124	Treatment	12	124	RECOVERING/ RESOLVING	NA	No

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[redacted]	F	60	右側の急性腎盂腎炎	急性腎盂腎炎	196	Treatment	1	196	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	35	右大腿外傷	四肢損傷	178	Treatment	10	178	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	46	チャーグ・ストラウス症候群	好酸球性多発血管炎性肉芽腫症	320	Treatment	15	320	NOT RECOVERED/ NOT RESOLVED	DRUG WITHDRAWN	No
[redacted]	M	74	鼻腫瘍-組織学的所見により基底細胞癌の増大と確定されたもの	基底細胞癌	113	Treatment	1	162	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No
			喘息増悪	喘息	194	Post-treatment	54	225	RECOVERED/ RESOLVED	NA	No

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[redacted]	F	21	気管支喘息の増悪	喘息	8	Treatment	8	8	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			気管支喘息の増悪	喘息	212	Treatment	18	212	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	40	急性期の2度の変形性右膝関節症	変形性関節症	44	Treatment	16	44	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			右膝関節の滑膜炎	滑膜炎	44	Treatment	16	44	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	43	喘息増悪	喘息	19	Treatment	19	19	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	48	喘息増悪	喘息	5	Treatment	5	6	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	176	Treatment	8	176	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	66	広範囲に及ぶ骨軟骨症	骨端症	46	Treatment	20	46	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			循環失調脳症	血管性脳症	46	Treatment	20	46	NOT RECOVERED/ NOT RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	74	急性腹膜炎	腹膜炎	247	Treatment	23	247	RECOVERED/ RESOLVED	NA	No

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[redacted]	F	39	右下腿の蜂巣炎、膿瘍(切開排膿後)	処置後合併症	43	Treatment	16	48	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	43	喘息増悪	喘息	55	Treatment	27	55	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	50	喘息の急性増悪	喘息	226	Post-treatment	226	227	RECOVERED/ RESOLVED	NA	No
[redacted]	M	65	喘息増悪	喘息	124	Treatment	13	124	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	53	喘息増悪	喘息	303	Treatment	20	304	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	M	59	出血性脳卒中	出血性卒中	93	Treatment	10	93	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	63	臍ヘルニアの悪化	臍ヘルニア	215	Treatment	21	215	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	28	喘息増悪	喘息	87	Treatment	1	104	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	143	Treatment	3	153	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	214	Treatment	18	214	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	28	喘息増悪	喘息	252	Treatment	26	252	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	274	Treatment	22	274	RECOVERED/ RESOLVED	DRUG WITHDRA-WN	No
[redacted]	M	52	喘息増悪	喘息	144	Treatment	4	144	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	49	喘息増悪	喘息	35	Treatment	6	35	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	35	喘息増悪	喘息	50	Treatment	25	51	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	54	関節リウマチの増悪	関節リウマチ	103	Treatment	17	103	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			狭心症	狭心症	111	Treatment	25	111	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	54	喘息増悪	喘息	275	Treatment	23	277	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	70	慢性結石性腎盂腎炎の急性増悪	急性腎盂腎炎	297	Treatment	3	299	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	43	両側性肺炎	肺炎	298	Treatment	18	301	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	47	喘息増悪	喘息	222	Treatment	1	223	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	291	Treatment	11	293	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	69	喘息増悪	喘息	287	Treatment	7	287	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	29	妊娠による悪心	妊娠嘔吐	90	Post-treatment	76	90	RECOVERED/ RESOLVED	NA	No
			うつ病の悪化	うつ病	124	Post-treatment	110	124	RECOVERED/ RESOLVED	NA	No

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[redacted]	F	29	片頭痛	片頭痛	220	Post-treatment	206	221	RECOVERED/ RESOLVED	NA	No
			妊娠中の患者の前期破水	前期破水	245	Post-treatment	231	245	RECOVERED/ RESOLVED	NA	No
[redacted]	M	53	急性うつ病エピソードの悪化	うつ病	-14	Pre-treatment		-14	RECOVERED/ RESOLVED	NA	No
			手根管症候群	手根管症候群	358	Treatment	11		RECOVERED/ RESOLVED	NA	No
[redacted]	F	29	急性気管支炎	気管支炎	16	Treatment	2	16	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

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Subject identi-tifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investi-gational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	65	喘息増悪	喘息	167	Treatment	1	167	RECOVERED/ RESOLVED	DRUG INTERRU-PTED	No
[redacted]	M	45	急性心筋梗塞	急性心筋梗塞	112	Treatment	28	112	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	61	喘息増悪	喘息	308	Treatment	14	308	RECOVERED/ RESOLVED	DRUG INTERRU-PTED	No
[redacted]	F	32	神経根障害	神経根障害	110	Treatment	12	110	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			下痢	下痢	331	Treatment	10	331	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
Q2W = Every 2 weeks, Q4W = Every 4 weeks.
MedDRA version 19.1.

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PSC1
Table 11.3.4.2.1 Serious adverse events - key subject information (Safety analysis set)

Group = Placebo											
Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	41	喘息増悪	喘息	125	Treatment	1	126	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	61	呼吸困難	呼吸困難	35	Treatment	3	35	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	54	喘息増悪	喘息	29	Treatment	29	29	RECOVERED/ RESOLVED	DRUG INTERRU-PTED	No
			喘息増悪	喘息	155	Treatment	14	155	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	275	Treatment	21	275	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	M	54	喘息増悪	喘息	359	Treatment	20	359	RECOVERED/ RESOLVED	NA	No
[redacted]	M	54	喘息増悪	喘息	302	Treatment	8	302	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	58	膝痛	関節痛	307	Treatment	1	307	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	58	喘息増悪	喘息	169	Treatment	30	169	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	F	67	子宮癌	子宮癌	149	Treatment	8	149	RECOVERED/ RESOLVED	DRUG WITHDRAWN	No

[a] Age at study entry
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	60	喘息増悪	喘息	68	Treatment	12	68	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	M	67	高血圧の悪化	高血圧	318	Treatment	9	319	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	61	喘息増悪	喘息	128	Treatment	1	128	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			腰部脊柱管狭窄症	腰部脊柱管狭窄症	297	Post-treatment	28	311	RECOVERING/ RESOLVING	NA	No
[redacted]	F	46	鼻骨骨折	顔面骨骨折	357	Treatment	6	357	RECOVERED/ RESOLVED	NA	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	64	肺炎	肺炎	275	Treatment	7	275	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			肺炎	肺炎	361	Treatment	11	361	RECOVERED/ RESOLVED	NA	No
[redacted]	F	30	右手第3および第4指 弾発指	弾発指	43	Treatment	15	43	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			帯状疱疹(左背部痛)	帯状疱疹	358	Treatment	21	358	RECOVERING/ RESOLVING	NA	No
[redacted]	M	26	自動車事故による腰頚部痛	外傷後疼痛	294	Treatment	14	294	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	F	53	胃腸炎	胃腸炎	43	Treatment	16	43	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			頚部リンパ節腫脹	リンパ節症	177	Treatment	10	320	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	52	喘息悪化	喘息	113	Treatment	1	114	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	31	頭部裂傷	裂傷	238	Treatment	14	238	RECOVERED/ RESOLVED WITH SEQUELAE	DRUG INTERRU-PTED	No
[redacted]	M	42	喘息増悪	喘息	201	Treatment	33	201	RECOVERED/ RESOLVED	DRUG INTERRU-PTED	No

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[b] As assessed by the investigator.
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	40	気管支喘息の増悪	喘息	315	Treatment	9	315	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	67	不整脈	不整脈	9	Treatment	9	9	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			不整脈 洞不全症候群	洞結節機能不全	23	Treatment	8	23	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			洞不全症候群	洞結節機能不全	34	Treatment	2	34	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	110	Treatment	12	110	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

[a] Age at study entry
[b] As assessed by the investigator.
NA=Not Applicable.
Time from last dose to AE is the time from the dose prior to the AE start date.
The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
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Subject identifier	Sex	Age[a] (yrs)	Episode term as reported by the investigator	Adverse event (MedDRA preferred term)	Time from first dose to AE (days)	Time Period	Time from last dose to AE (days)	Time from first dose to becoming serious (days)	Outcome	Action taken (with investigational product)	Reasonable possibility AE causally related to tralokinumab [b]
[redacted]	M	67	喘息増悪	喘息	216	Treatment	6	216	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	45	喘息増悪	喘息	9	Treatment	9	10	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	85	Treatment	15	85	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
[redacted]	M	45	喘息増悪	喘息	76	Treatment	15	76	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	268	Treatment	16	268	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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[redacted]	F	66	肺炎	肺炎	24	Treatment	7	24	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No
			肺炎	肺炎	347	Treatment	12	347	RECOVERED/ RESOLVED	DRUG INTERRUPTED	Yes
[redacted]	F	42	喘息増悪	喘息	220	Treatment	12	220	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	355	Treatment	4	355	RECOVERED/ RESOLVED	NA	No
[redacted]	M	68	ステント留置を伴う心筋梗塞	心筋梗塞	41	Treatment	10	41	RECOVERED/ RESOLVED	DRUG INTERRUPTED	No

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The Placebo treatment group is a pooled treatment group (Placebo Q2W + Placebo Q4W).
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[redacted]	M	74	貧血	貧血	68	Treatment	13	68	NOT RECOVERED/ NOT RESOLVED	DOSE NOT CHANGED	No
			体液量減少	血液量減少症	68	Treatment	13	68	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			逆流性食道炎の悪化	胃食道逆流性疾患	91	Treatment	6	91	RECOVERED/ RESOLVED	NA	No
			肺炎	肺炎	91	Treatment	6	91	RECOVERED/ RESOLVED	NA	No
			急性前立腺炎	前立腺炎	91	Treatment	6	91	NOT RECOVERED/ NOT RESOLVED	NA	No

[a] Age at study entry
[b] As assessed by the investigator.
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[redacted]	M	74	非ST上昇型心筋梗塞	急性心筋梗塞	95	Treatment	10	95	RECOVERED/ RESOLVED	NA	No
[redacted]	F	13	喘息増悪	喘息	121	Treatment	8	121	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	331	Treatment	22	331	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	62	右眼の白内障の悪化	白内障	26	Treatment	12	57	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	F	63	胆石	胆石症	-24	Pre-treatment		36	RECOVERED/ RESOLVED	NA	No

[a] Age at study entry
[b] As assessed by the investigator.
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[redacted]	F	63	急性喘息増悪	喘息	237	Treatment	12	238	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
[redacted]	M	47	喘息増悪	喘息	54	Treatment	26	54	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No
			喘息増悪	喘息	163	Treatment	23	163	RECOVERED/ RESOLVED	DOSE NOT CHANGED	No

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1.14.2.3　個別症例の詳細

死亡および重篤な有害事象の詳細を，［M5.3.5.4 D2210C00007/STRATOS 1 11.4 項］に示す。

1.14.2.3.1　死亡症例

治験実施計画書／被験者登録コード：	D2210C00007/[redacted]
年齢／性別／人種／民族／国：	54歳／女性／白人／ヒスパニックまたはラテン系／アルゼンチン
治験薬の用量および投与レジメン：	トラロキヌマブ300 mg，4週間隔
治験薬の初回投与日（時刻）：	20[redacted]-08-19 (10:30)
治験薬の最終投与日（時刻）：	翌年*-03-03 (10:15)
SAE（基本語）：	喘息および脳血管障害
事象発現日（時刻）：	翌年*-03-09 (19:00)
死亡日：	翌年*-04-02
事象発現前の最終投与から事象発現までの期間（日数）：	6日
事象発現までの治験薬の総投与回数：	9回（全9回中）
事象の転帰：	致死的
治験薬（継続／中止）：	治験薬および治験の中止
因果関係（あり／なし）：	なし

被験者[redacted]は，アルゼンチン出身の 54 歳白人女性で，喘息を有していた。被験者は胃食道逆流性疾患も有していた 。現病歴は，甲状腺機能低下症，変形性関節症および背部痛であった。事象発現時の関連する併用治療薬は，サルメテロール，フルチカゾン，サルブタモール，レボチロキシン，トラマドール，パラセタモール，グルコサミン，メロキシカム，およびプレガバリンであった。被験者は，Q4W の投与レジメン（予定総投与回数 13 回）のトラロキヌマブ投与群に無作為に割り付けられた。

翌＊年 3 月 9 日，トラロキヌマブの 9 回目の投与（投与済 9 回中）から 7 日後，被験者は呼吸困難，チアノーゼおよび感覚消失を訴えて来院した。被験者は，重篤な有害事象の喘息（急性の喘息の増悪）を発症し，入院した。被験者は，低酸素血症と筋肉疲労のため機械的換気を受けた。被験者は，フェンタニル 250 mg および用量不明の静脈内投与，サクシニルコリン／パブロン，平衡電解質，およびブスコパンヒヨスチン 60 mg の 1 日 1 回静脈内投与による治療を受けた。胸部X 線は正常であった。被験者は感覚抑制を示した。脳のコンピュータ断層撮影から虚血性病変が明らかになり，被験者は脳血管障害の重篤な有害事象と診断された。被験者は入院期間

＊ 新薬承認情報提供時に置き換え

中に以下の治療を受けた：ブデソニド 1080 μg および 1200 μg のネブライザー吸入，サルブタモール（用量不明）のネブライザー吸入，ヒドロコルチゾン 400 mg および 1000 mg の静脈内投与，プレドニゾン 40 mg の 1 日 1 回経口投与，イプラトロピウム 1.12 mg の吸入，アミノフィリン 480 mg の 1 日 1 回静脈内投与，塩化ナトリウム 3500 mL および 1000 mL の静脈内投与，エピネフリン 3000 μg の静脈内投与，プロポフォール 10 mg の静脈内投与，パンクロニウム 4 mg の静脈内投与，スキサメトニウム 100 mg の静脈内投与，スルタミシリン 6 g の 1 日 1 回静脈内投与，アンピシリン 6 mg の 1 日 1 回静脈内投与，シプロフロキサシン 400 mg の 1 日 1 回静脈内投与，バンコマイシン 1 gm の 1 日 1 回静脈内投与，コリスチン 300 mg の 1 日 1 回静脈内投与，メロペネム 3 gm の 1 日 1 回静脈内投与，スルバクタム／アンピシリン 6 gm の静脈内投与，ジアゼパム（用量不明）の静脈内投与，メタミゾール 1 gm の 1 日 1 回静脈内投与，フェニトインの 1 日 1 回静脈内投与（翌＊年 3 月 22 日に 150 mg，翌＊年 3 月-31 日に 50 mg），フロセミド 20 mg は 1 日 2 回の静脈内投与後に 1 日 1 回の静脈内投与，ミダゾラム 450 mg の静脈内投与，アセチルシステイン 600 mg の 1 日 1 回経口投与，パラセタモール（用量不明）の経腸投与，ラニチジン 150 mg の 1 日 1 回投与，メトクロプロミド 30 mg の 1 日 1 回静脈内投与，ドンペリドン 10 mg の 1 日 1 回静脈内投与，ヘパリン 10000 IU の 1 日 1 回皮下投与，5%デキストロース溶液 1000 mL の静脈内投与，マンニトール150 mL の1 日1 回静脈内投与，ドーパミン（用量不明）の静脈内投与およびアスコルビン酸 1 gm の 1 日 1 回筋肉内投与。翌＊年 4 月 2 日，被験者は死亡した。剖検は実施されなかった。主な死因は喘息と報告され，二次的死因は脳虚血と報告された。

本事象の重症度は，治験担当医師により重度と判断され，転帰は致死的であった。治験薬は，喘息および脳血管障害の事象によって永続的に中止となり，最終投与日は 翌＊年 3 月 3 日であった。治験担当医師は，この致死的事象を治験薬と「関連なし」と評価した。翌＊年 4 月 2 日，被験者は死亡により本治験を中止した。

喘息および脳血管障害の事象は外部の判定委員会に送られ，その評価は「肺感染による呼吸不全，喘息，脳虚血／発作の可能性，多臓器不全，低血圧，および最終的な死亡（肺疾患が心停止，脳卒中および肺炎に至ったことによる二次的な非心血管系の死亡）」であった。

治験実施計画書／被験者登録コード：	D2210C00007/[redacted]
年齢／性別／人種／民族／国：	60歳／女性／白人／非ヒスパニックまたはラテン系／ポーランド
治験薬の用量および投与レジメン：	トラロキヌマブ300 mg，2週間隔
治験薬の初回投与日（時刻）：	20[redacted]-05-05 (09:20)
治験薬の最終投与日（時刻）：	同年*-06-02 (07:50)
SAE（基本語）：	感染性下痢
事象発現日（時刻）：	同年*-06-08（時刻不明）

＊ 新薬承認情報提供時に置き換え

事象発現前の最終投与から事象発現までの期間（日数）：	6日
事象発現までの治験薬の総投与回数	3回（全3回中）
事象の転帰	致死的
治験薬（継続／中止）	治験薬および治験の中止
因果関係（あり／なし）	なし

被験者[redacted]は，ポーランド出身の60歳白人女性で，運動，ウイルス感染，細菌感染が誘因となる喘息を有していた。被験者は胃食道逆流性疾患も有していた。現病歴は，脳血管不全，変形性脊椎症，椎間板障害（脊椎の椎間板障害），骨粗鬆症，末梢静脈疾患および緑内障であった。既往歴は全身性塞栓症であった。事象発現時の関連する併用治療薬は，サルメテロール，フォルモテロール，ベクロメタゾン，フルチカゾン，テオフィリン，ニセルゴリン，ジクロフェナク，アレンドロネート，ブリンゾラミド，アロプリノール，シアノコバラミン，塩化カリウム，およびパントプラゾールであった。事象発現前の関連する薬剤にはプレドニゾンがあった。被験者は，Q2Wの投与レジメン（予定総投与回数26回）のトラロキヌマブ投与群に無作為に割り付けられた。

同＊年6月4日，被験者に非重篤な有害事象の感染性下痢が発現した。同＊年6月8日，トラロキヌマブの3回目の投与（投与済3回中）から6日後，被験者は来院し，当該事象は，脱水，腎機能不全，多臓器不全および肺水腫によって重篤であると報告された。血液培養の結果はBacteroides fragilis陽性であった。被験者は同日に入院した。入院期間中，被験者は以下の治療を受けた（用量は不明）：セフロキシムの静脈内投与および経口投与，シプロフロキサシンの経口投与，エノキサパリンの皮下投与，メトクロプラミドの経口投与，ロペラミドの経口投与，乳酸桿菌の経口投与，フロセミドの経口投与およびドロタベリンの経口投与。

同＊年6月2日，感染性下痢の事象により治験薬は永続的に中止され，この日の投与が中止前の最終投与となった。同＊年6月10日，被験者は死亡した。剖検報告から，敗血症，大腸ループと腹膜への化膿性浸潤，両側肺水腫および多臓器不全が示された。主な死因は細菌性腸炎と報告された。二次的死因は敗血症と報告された。

本事象の重症度は，治験担当医師により重度と判断され，転帰は致死的であった。同*年6月2日の事象により，治験薬は永続的に中止となった。治験担当医師は，本事象を治験薬と「関連なし」と評価した。

感染性下痢の事象は外部の判定委員会に送られ，その評価は「敗血症および多臓器不全に伴う腸からの化膿性感染」であった。

＊ 新薬承認情報提供時に置き換え