インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
16. 特別な患者集団における安全性（試験別）

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7.16 Safety in special groups by trial

7.16.1 Adverse events by sex - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	197				229			
Male	295				263			
PYE (years)								
Female	193.94				225.98			
Male	291.94				259.06			
Events								
Female	145	(73.6)	540	278.44	163	(71.2)	616	272.59
Male	206	(69.8)	687	235.32	172	(65.4)	546	210.77
Serious								
Yes								
Female	20	(10.2)	26	13.41	24	(10.5)	31	13.72
Male	31	(10.5)	48	16.44	25	(9.5)	42	16.21
No								
Female	141	(71.6)	514	265.04	159	(69.4)	585	258.87
Male	197	(66.8)	639	218.88	169	(64.3)	504	194.55
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	8	(4.1)	10	5.16	12	(5.2)	14	6.20
Male	10	(3.4)	16	5.48	8	(3.0)	20	7.72
Moderate								
Female	61	(31.0)	119	61.36	70	(30.6)	140	61.95
Male	91	(30.8)	161	55.15	66	(25.1)	111	42.85
Mild								
Female	123	(62.4)	411	211.93	138	(60.3)	462	204.44
Male	169	(57.3)	510	174.69	148	(56.3)	415	160.20
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	8	(4.1)	10	5.16	11	(4.8)	20	8.85
Male	11	(3.7)	17	5.82	18	(6.8)	25	9.65
Possible								
Female	18	(9.1)	24	12.38	16	(7.0)	25	11.06
Male	16	(5.4)	22	7.54	15	(5.7)	21	8.11
Unlikely								
Female	143	(72.6)	506	260.91	162	(70.7)	570	252.24
Male	200	(67.8)	647	221.62	163	(62.0)	500	193.01
Missing								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Related to technical complaint for basal insulin								
Yes								
Female	0				0			
Male	0				0			
No								
Female	145	(73.6)	540	278.44	163	(71.2)	615	272.15
Male	205	(69.5)	686	234.98	172	(65.4)	546	210.77
NA								
Female	0				0			
Male	0				0			
Missing								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				1	(0.4)	1	0.44
Male	4	(1.4)	5	1.71	1	(0.4)	2	0.77
Not recovered/not resolved								
Female	63	(32.0)	133	68.58	79	(34.5)	144	63.72
Male	94	(31.9)	191	65.42	80	(30.4)	146	56.36
Recovered/resolved with sequelae								
Female	3	(1.5)	3	1.55	3	(1.3)	4	1.77
Male	3	(1.0)	3	1.03	2	(0.8)	2	0.77
Recovering/resolving								
Female	9	(4.6)	14	7.22	10	(4.4)	10	4.43
Male	10	(3.4)	12	4.11	10	(3.8)	11	4.25
Recovered/resolved								
Female	133	(67.5)	390	201.10	152	(66.4)	457	202.23
Male	175	(59.3)	476	163.05	141	(53.6)	385	148.62
Unknown								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.2 Adverse events by sex - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	101				123			
Male	161				140			
PYE (years)								
Female	59.80				70.42			
Male	95.44				82.35			
Events								
Female	63	(62.4)	211	352.83	62	(50.4)	146	207.33
Male	98	(60.9)	255	267.17	72	(51.4)	182	221.00
Serious								
Yes								
Female	7	(6.9)	11	18.39	6	(4.9)	9	12.78
Male	15	(9.3)	19	19.91	10	(7.1)	11	13.36
No								
Female	61	(60.4)	200	334.43	60	(48.8)	137	194.55
Male	97	(60.2)	236	247.26	68	(48.6)	171	207.65
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	2	(2.0)	4	6.69	6	(4.9)	7	9.94
Male	9	(5.6)	13	13.62	5	(3.6)	6	7.29
Moderate								
Female	24	(23.8)	39	65.21	24	(19.5)	38	53.96
Male	40	(24.8)	83	86.96	30	(21.4)	44	53.43
Mild								
Female	57	(56.4)	168	280.92	51	(41.5)	101	143.42
Male	75	(46.6)	159	166.59	58	(41.4)	132	160.29
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	4	(4.0)	4	6.69	2	(1.6)	3	4.26
Male	5	(3.1)	5	5.24	4	(2.9)	10	12.14
Possible								
Female	8	(7.9)	17	28.43	5	(4.1)	5	7.10
Male	8	(5.0)	9	9.43	2	(1.4)	2	2.43
Unlikely								
Female	62	(61.4)	185	309.35	61	(49.6)	137	194.55
Male	93	(57.8)	236	247.26	69	(49.3)	168	204.00
Missing								
Female	3	(3.0)	5	8.36	1	(0.8)	1	1.42
Male	3	(1.9)	5	5.24	2	(1.4)	2	2.43
Related to technical complaint for basal insulin								
Yes								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			
No								
Female	63	(62.4)	204	341.12	61	(49.6)	144	204.49
Male	97	(60.2)	250	261.93	70	(50.0)	179	217.36
NA								
Female	1	(1.0)	1	1.67	0			
Male	0				1	(0.7)	1	1.21
Missing								
Female	3	(3.0)	5	8.36	1	(0.8)	1	1.42
Male	3	(1.9)	5	5.24	2	(1.4)	2	2.43

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				1	(0.8)	1	1.42
Male	2	(1.2)	3	3.14	1	(0.7)	1	1.21
Not recovered/not resolved								
Female	21	(20.8)	42	70.23	21	(17.1)	24	34.08
Male	34	(21.1)	55	57.63	27	(19.3)	39	47.36
Recovered/resolved with sequelae								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Recovering/resolving								
Female	8	(7.9)	9	15.05	6	(4.9)	7	9.94
Male	11	(6.8)	15	15.72	10	(7.1)	10	12.14
Recovered/resolved								
Female	54	(53.5)	160	267.55	46	(37.4)	114	161.89
Male	81	(50.3)	182	190.69	54	(38.6)	131	159.07
Unknown								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.3 Adverse events by sex - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	137				141			
Male	154				150			
PYE (years)								
Female	79.05				80.56			
Male	88.31				86.23			
Events								
Female	86	(62.8)	209	264.38	80	(56.7)	304	377.34
Male	85	(55.2)	246	278.57	87	(58.0)	246	285.27
Serious								
Yes								
Female	9	(6.6)	9	11.38	12	(8.5)	17	21.10
Male	13	(8.4)	26	29.44	13	(8.7)	16	18.55
No								
Female	83	(60.6)	200	253.00	79	(56.0)	287	356.24
Male	81	(52.6)	220	249.12	81	(54.0)	230	266.72
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	3	(2.2)	3	3.79	5	(3.5)	6	7.45
Male	10	(6.5)	17	19.25	7	(4.7)	8	9.28
Moderate								
Female	32	(23.4)	52	65.78	31	(22.0)	64	79.44
Male	27	(17.5)	47	53.22	30	(20.0)	57	66.10
Mild								
Female	69	(50.4)	154	194.81	72	(51.1)	234	290.45
Male	69	(44.8)	182	206.09	76	(50.7)	181	209.89
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	3	(2.2)	3	3.79	2	(1.4)	2	2.48
Male	6	(3.9)	10	11.32	5	(3.3)	6	6.96
Possible								
Female	9	(6.6)	12	15.18	10	(7.1)	36	44.68
Male	14	(9.1)	22	24.91	7	(4.7)	7	8.12
Unlikely								
Female	82	(59.9)	194	245.41	79	(56.0)	266	330.17
Male	75	(48.7)	214	242.33	83	(55.3)	233	270.19
Missing								
Female	0				0			
Male	0				0			
Related to technical complaint for basal insulin								
Yes								
Female	3	(2.2)	3	3.79	2	(1.4)	3	3.72
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
No								
Female	85	(62.0)	206	260.59	80	(56.7)	301	373.62
Male	85	(55.2)	244	276.30	87	(58.0)	244	282.95
NA								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				1	(0.7)	1	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				0			
Male	2	(1.3)	4	4.53	1	(0.7)	1	1.16
Not recovered/not resolved								
Female	39	(28.5)	66	83.49	32	(22.7)	82	101.78
Male	39	(25.3)	73	82.66	41	(27.3)	70	81.17
Recovered/resolved with sequelae								
Female	0				2	(1.4)	2	2.48
Male	0				0			
Recovering/resolving								
Female	7	(5.1)	10	12.65	8	(5.7)	11	13.65
Male	9	(5.8)	22	24.91	8	(5.3)	11	12.76
Recovered/resolved								
Female	72	(52.6)	133	168.24	69	(48.9)	209	259.42
Male	71	(46.1)	147	166.46	73	(48.7)	164	190.18
Unknown								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.4 Adverse events by sex - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	125				120			
Male	165				172			
PYE (years)								
Female	61.37				59.03			
Male	80.94				85.09			
Events								
Female	85	(68.0)	219	356.87	82	(68.3)	242	409.94
Male	104	(63.0)	288	355.81	108	(62.8)	377	443.08
Serious								
Yes								
Female	4	(3.2)	5	8.15	5	(4.2)	7	11.86
Male	7	(4.2)	10	12.35	2	(1.2)	2	2.35
No								
Female	84	(67.2)	214	348.73	80	(66.7)	235	398.08
Male	101	(61.2)	278	343.46	107	(62.2)	375	440.73
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	5	(4.0)	5	8.15	3	(2.5)	4	6.78
Male	4	(2.4)	5	6.18	1	(0.6)	1	1.18
Moderate								
Female	20	(16.0)	37	60.29	21	(17.5)	37	62.68
Male	31	(18.8)	53	65.48	30	(17.4)	52	61.11
Mild								
Female	74	(59.2)	177	288.43	78	(65.0)	201	340.48
Male	95	(57.6)	230	284.15	92	(53.5)	324	380.79
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	7	(5.6)	8	13.04	3	(2.5)	3	5.08
Male	10	(6.1)	12	14.83	4	(2.3)	5	5.88
Possible								
Female	5	(4.0)	5	8.15	7	(5.8)	9	15.25
Male	17	(10.3)	21	25.94	10	(5.8)	32	37.61
Unlikely								
Female	82	(65.6)	206	335.69	81	(67.5)	230	389.61
Male	96	(58.2)	255	315.04	108	(62.8)	340	399.59
Missing								
Female	0				0			
Male	0				0			
Related to technical complaint for basal insulin								
Yes								
Female	0				0			
Male	0				0			
No								
Female	85	(68.0)	219	356.87	82	(68.3)	242	409.94
Male	104	(63.0)	288	355.81	108	(62.8)	377	443.08
NA								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Not recovered/not resolved								
Female	33	(26.4)	57	92.89	35	(29.2)	66	111.80
Male	53	(32.1)	77	95.13	48	(27.9)	78	91.67
Recovered/resolved with sequelae								
Female	0				1	(0.8)	1	1.69
Male	0				2	(1.2)	2	2.35
Recovering/resolving								
Female	5	(4.0)	5	8.15	2	(1.7)	4	6.78
Male	1	(0.6)	1	1.24	3	(1.7)	4	4.70
Recovered/resolved								
Female	72	(57.6)	157	255.84	73	(60.8)	171	289.67
Male	88	(53.3)	209	258.21	88	(51.2)	293	344.35
Unknown								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.5 Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	197				229			
Male	295				263			
PYE (years)								
Female	193.94				225.98			
Male	291.94				259.06			
Events								
Female	145	(73.6)	540	278.44	163	(71.2)	616	272.59
Male	206	(69.8)	687	235.32	172	(65.4)	546	210.77
Blood and lymphatic system disorders								
All								
Female	5	(2.5)	5	2.58	6	(2.6)	6	2.66
Male	6	(2.0)	6	2.06	5	(1.9)	5	1.93
Anaemia								
Female	3	(1.5)	3	1.55	3	(1.3)	3	1.33
Male	3	(1.0)	3	1.03	3	(1.1)	3	1.16
Blood loss anaemia								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Eosinophilia								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Hypochromic anaemia								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Iron deficiency anaemia								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Lymphadenopathy								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Polycythaemia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Thrombocytopenia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	13	(6.6)	20	10.31	13	(5.7)	16	7.08
Male	24	(8.1)	43	14.73	17	(6.5)	22	8.49
Acute coronary syndrome								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Acute myocardial infarction								
Female	0				2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	2	(0.8)	2	0.77
Angina pectoris								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Angina unstable								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Aortic valve calcification								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Aortic valve incompetence								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Arrhythmia								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Atrial fibrillation								
Female	2	(1.0)	3	1.55	1	(0.4)	1	0.44
Male	6	(2.0)	6	2.06	3	(1.1)	3	1.16
Atrial flutter								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Atrial thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Atrioventricular block complete								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Bradycardia								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Bundle branch block right								
Female	0				0			
Male	1	(0.3)	1	0.34	2	(0.8)	3	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac dysfunction								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Cardiac failure								
Female	1	(0.5)	1	0.52	0			
Male	3	(1.0)	3	1.03	0			
Cardiac failure chronic								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Cardiac failure congestive								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Cardiac ventricular thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Chronic coronary syndrome								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Coronary artery disease								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39
Coronary artery occlusion								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Diastolic dysfunction								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Left atrial dilatation								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Left ventricular dysfunction								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Left ventricular hypertrophy								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Mitral valve incompetence								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Myocardial infarction								
Female	0				1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Palpitations								
Female	3	(1.5)	3	1.55	3	(1.3)	3	1.33
Male	0				0			
Pericardial effusion								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Pericarditis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Sinus arrhythmia								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Sinus bradycardia								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Sinus tachycardia								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Supraventricular extrasystoles								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Tachycardia								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Tricuspid valve incompetence								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Ventricular extrasystoles								
Female	2	(1.0)	2	1.03	0			
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
Female	0				1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Congenital syphilitic osteochondritis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hydrocele								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Type V hyperlipidaemia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Female	3	(1.5)	3	1.55	4	(1.7)	4	1.77
Male	5	(1.7)	5	1.71	5	(1.9)	6	2.32
Ear inflammation								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Ear pain								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Eustachian tube dysfunction								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Hypoacusis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Presbyacusis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Tinnitus								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Vertigo								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	3	(1.1)	4	1.54
Vertigo positional								
Female	0				0			
Male	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Female	1	(0.5)	1	0.52	3	(1.3)	3	1.33
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Goitre								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Hyperplasia adrenal								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hyperprolactinaemia								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hyperthyroidism								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Hypothyroidism								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Thyroid mass								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Eye disorders								
All								
Female	11	(5.6)	13	6.70	10	(4.4)	11	4.87
Male	14	(4.7)	22	7.54	15	(5.7)	21	8.11
Acquired epiblepharon								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Asthenopia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Astigmatism								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Blepharitis								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
Female	4	(2.0)	5	2.58	1	(0.4)	1	0.44
Male	5	(1.7)	6	2.06	3	(1.1)	4	1.54
Conjunctival erosion								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Conjunctival haemorrhage								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Conjunctivitis allergic								
Female	1	(0.5)	2	1.03	0			
Male	0				0			
Dacryoadenitis acquired								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Diabetic retinal oedema								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Diabetic retinopathy								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	2	(0.8)	2	0.77
Diplopia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Dry eye								
Female	0				3	(1.3)	3	1.33
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77
Eye discharge								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Eye inflammation								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Eye pain								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Glaucoma								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Macular oedema								
Female	0				0			
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal tension glaucoma								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Ocular hypertension								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Optic disc vascular disorder								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Photophobia								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Post thrombotic retinopathy								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Posterior capsule opacification								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Retinal aneurysm								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Retinal artery occlusion								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Retinal detachment								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Retinal tear								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Retinal vein occlusion								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Scintillating scotoma								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Uveitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Vision blurred								
Female	0				0			
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Vitreous detachment								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Vitreous haemorrhage								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Gastrointestinal disorders								
All								
Female	37	(18.8)	65	33.52	42	(18.3)	67	29.65
Male	46	(15.6)	71	24.32	32	(12.2)	47	18.14
Abdominal discomfort								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Abdominal distension								
Female	2	(1.0)	2	1.03	0			
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39
Abdominal pain								
Female	3	(1.5)	3	1.55	4	(1.7)	4	1.77
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Abdominal pain lower								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Abdominal pain upper								
Female	0				4	(1.7)	5	2.21
Male	2	(0.7)	2	0.69	0			
Acid peptic disease								
Female	0				0			
Male	0				2	(0.8)	2	0.77
Anal fissure								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Anal pruritus								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Chronic gastritis								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Colitis								

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Colitis ischaemic								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Colitis microscopic								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Constipation								
Female	2	(1.0)	2	1.03	5	(2.2)	5	2.21
Male	2	(0.7)	2	0.69	0			
Crohn's disease								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Dental caries								
Female	2	(1.0)	3	1.55	0			
Male	4	(1.4)	5	1.71	1	(0.4)	1	0.39
Diarrhoea								
Female	17	(8.6)	24	12.38	13	(5.7)	14	6.20
Male	14	(4.7)	19	6.51	8	(3.0)	8	3.09
Diverticulum								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Diverticulum intestinal								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Dry mouth								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Duodenitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Dyspepsia								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			
Enteritis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Enterocolitis								
Female	0				0			
Male	3	(1.0)	4	1.37	0			
Epigastric discomfort								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.4)	1	0.39
Flatulence								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Food poisoning								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Frequent bowel movements								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Gastric disorder								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Gastric polyps								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Gastrointestinal inflammation								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Gastrooesophageal reflux disease								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	4	(1.4)	4	1.37	4	(1.5)	4	1.54
Haematochezia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Haemorrhoids								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Hiatus hernia								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hyperaesthesia teeth								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Hyperchlorhydria								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Ileus								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Inguinal hernia								
Female	0				0			
Male	0				1	(0.4)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Intra-abdominal haematoma								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Irritable bowel syndrome								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Large intestine polyp								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	2	0.77
Loose tooth								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Melaena								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Nausea								
Female	9	(4.6)	10	5.16	2	(0.9)	3	1.33
Male	6	(2.0)	6	2.06	3	(1.1)	4	1.54
Oral discomfort								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Pancreatitis								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Pancreatitis acute								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Pancreatitis chronic								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Periodontal disease								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Periodontal inflammation								
Female	0				0			
Male	0				1	(0.4)	2	0.77
Rectal polyp								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Rectal prolapse								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Stomatitis								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Tooth disorder								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Tooth impacted								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Toothache								
Female	3	(1.5)	3	1.55	1	(0.4)	1	0.44
Male	6	(2.0)	6	2.06	1	(0.4)	1	0.39
Ulcerative gastritis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Umbilical hernia								
Female	0				0			
Male	0				2	(0.8)	2	0.77
Vomiting								
Female	1	(0.5)	1	0.52	4	(1.7)	6	2.66
Male	3	(1.0)	3	1.03	4	(1.5)	5	1.93
General disorders and administration site conditions								
All								
Female	24	(12.2)	42	21.66	39	(17.0)	53	23.45
Male	51	(17.3)	72	24.66	39	(14.8)	57	22.00
Asthenia								
Female	3	(1.5)	3	1.55	4	(1.7)	4	1.77
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Chest discomfort								
Female	3	(1.5)	3	1.55	0			
Male	0				1	(0.4)	1	0.39
Chest pain								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	3	(1.0)	3	1.03	0			
Chills								
Female	2	(1.0)	2	1.03	0			
Male	0				1	(0.4)	1	0.39
Death								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Discomfort								

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Drug intolerance								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Early satiety								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Fatigue								
Female	5	(2.5)	5	2.58	3	(1.3)	3	1.33
Male	8	(2.7)	9	3.08	2	(0.8)	2	0.77
Feeling abnormal								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	3	1.03	0			
Feeling hot								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Gait disturbance								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Hunger								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	3	(1.0)	4	1.37	0			
Implant site pruritus								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Inflammation								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Influenza like illness								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Injection site bruising								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Injection site dermatitis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Injection site erythema								
Female	1	(0.5)	1	0.52	0			
Male	0				4	(1.5)	4	1.54
Injection site haemorrhage								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.4)	1	0.39
Injection site hypersensitivity								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Injection site hypertrophy								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Injection site mass								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Injection site pain								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Injection site reaction								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Injection site urticaria								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Malaise								
Female	1	(0.5)	2	1.03	2	(0.9)	3	1.33
Male	4	(1.4)	4	1.37	6	(2.3)	7	2.70
Medical device site bruise								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	3	(1.0)	4	1.37	0			
Medical device site dermatitis								
Female	0				3	(1.3)	3	1.33
Male	2	(0.7)	5	1.71	5	(1.9)	11	4.25
Medical device site eczema								
Female	0				0			
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77
Medical device site erythema								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Medical device site haematoma								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Medical device site haemorrhage								
Female	0				2	(0.9)	2	0.89
Male	4	(1.4)	4	1.37	0			
Medical device site hypersensitivity								
Female	0				0			
Male	1	(0.3)	1	0.34	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site inflammation								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Medical device site pain								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Medical device site pruritus								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Medical device site reaction								
Female	0				0			
Male	1	(0.3)	3	1.03	1	(0.4)	1	0.39
Non-cardiac chest pain								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Oedema								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Oedema peripheral								
Female	3	(1.5)	3	1.55	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	4	(1.5)	5	1.93
Pain								
Female	2	(1.0)	2	1.03	3	(1.3)	3	1.33
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Peripheral swelling								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Procedural failure								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Pyrexia								
Female	5	(2.5)	5	2.58	11	(4.8)	12	5.31
Male	12	(4.1)	13	4.45	10	(3.8)	10	3.86
Swelling								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Thirst								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Vaccination site erythema								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	3	(1.0)	4	1.37	1	(0.4)	1	0.39
Vaccination site reaction								
Female	0				0			
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
Female	1	(0.5)	1	0.52	4	(1.7)	5	2.21
Male	8	(2.7)	11	3.77	2	(0.8)	2	0.77
Cholelithiasis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Gallbladder cholesterolosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Hepatic cirrhosis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Hepatic cyst								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hepatic function abnormal								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Hepatic steatosis								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	5	(1.7)	5	1.71	0			
Hypertransaminasaemia								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Liver disorder								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Non-alcoholic steatohepatitis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Nonalcoholic fatty liver disease								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Steatohepatitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Female	1	(0.5)	1	0.52	4	(1.7)	5	2.21
Male	2	(0.7)	3	1.03	1	(0.4)	1	0.39
Allergy to arthropod bite								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Immunisation reaction								
Female	0				1	(0.4)	2	0.89
Male	0				0			
Seasonal allergy								
Female	1	(0.5)	1	0.52	3	(1.3)	3	1.33
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Infections and infestations								
All								
Female	89	(45.2)	149	76.83	100	(43.7)	161	71.25
Male	80	(27.1)	114	39.05	93	(35.4)	126	48.64
Abscess								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Acarodermatitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Acute sinusitis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Anal abscess								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Asymptomatic COVID-19								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Bacterial infection								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Balanitis candida								
Female	0				0			
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Breast abscess								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Breast cellulitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Bronchitis								
Female	5	(2.5)	5	2.58	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	3	(1.1)	3	1.16
Candida infection								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Cellulitis								
Female	1	(0.5)	1	0.52	0			
Male	0				2	(0.8)	2	0.77
Chlamydial infection								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Chronic hepatitis C								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Chronic sinusitis								
Female	0				3	(1.3)	3	1.33
Male	0				0			
Chronic tonsillitis								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Clostridium difficile infection								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Conjunctivitis								
Female	3	(1.5)	3	1.55	0			
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Coronavirus infection								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	2	(0.8)	3	1.16
COVID-19								
Female	26	(13.2)	26	13.41	34	(14.8)	35	15.49
Male	23	(7.8)	23	7.88	27	(10.3)	27	10.42

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
Female	4	(2.0)	4	2.06	3	(1.3)	3	1.33
Male	0				0			
Cystitis								
Female	5	(2.5)	6	3.09	6	(2.6)	7	3.10
Male	0				2	(0.8)	2	0.77
Dermatophytosis of nail								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Diverticulitis								
Female	0				4	(1.7)	4	1.77
Male	0				0			
Ear infection								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Empyema								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Endophthalmitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Epididymitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Erysipelas								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Escherichia urinary tract infection								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Eye infection bacterial								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Folliculitis								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Fungal balanitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Fungal infection								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
Female	0				0			
Male	1	(0.3)	2	0.69	1	(0.4)	1	0.39
Gastroenteritis								
Female	2	(1.0)	2	1.03	3	(1.3)	3	1.33
Male	2	(0.7)	2	0.69	2	(0.8)	2	0.77
Gastroenteritis norovirus								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Gastroenteritis viral								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Gastrointestinal infection								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Genital infection fungal								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Giardiasis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Gingivitis								
Female	0				1	(0.4)	1	0.44
Male	2	(0.7)	3	1.03	0			
Helicobacter gastritis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Helicobacter infection								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Herpes dermatitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Herpes simplex								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Herpes virus infection								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Herpes zoster								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	5	(1.9)	5	1.93

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hordeolum								
Female	2	(1.0)	2	1.03	0			
Male	0				0			
Infected bite								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Influenza								
Female	0				1	(0.4)	1	0.44
Male	0				2	(0.8)	2	0.77
Labyrinthitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Laryngitis								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Laryngopharyngitis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Localised infection								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Lower respiratory tract infection								
Female	3	(1.5)	3	1.55	1	(0.4)	3	1.33
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Lyme disease								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Mastitis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Nail infection								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Nasopharyngitis								
Female	15	(7.6)	18	9.28	16	(7.0)	17	7.52
Male	15	(5.1)	18	6.17	18	(6.8)	20	7.72
Onychomycosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Oophoritis								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Oropharyngeal candidiasis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Osteomyelitis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Otitis externa								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Otitis media								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Otitis media acute								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Otitis media chronic								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Parotitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Peri-implantitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Pericoronitis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Periodontitis								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Pharyngitis								
Female	6	(3.0)	7	3.61	2	(0.9)	3	1.33
Male	5	(1.7)	6	2.06	7	(2.7)	8	3.09
Pharyngotonsillitis								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	2	0.77
Pneumonia								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post procedural infection								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Pulpitis dental								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Purulence								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Respiratory syncytial virus infection								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Respiratory tract infection								
Female	3	(1.5)	3	1.55	2	(0.9)	2	0.89
Male	0				2	(0.8)	2	0.77
Respiratory tract infection viral								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Rhinitis								
Female	2	(1.0)	2	1.03	3	(1.3)	3	1.33
Male	4	(1.4)	4	1.37	1	(0.4)	1	0.39
Rotavirus infection								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Salpingitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Sepsis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Sinusitis								
Female	6	(3.0)	7	3.61	5	(2.2)	7	3.10
Male	0				1	(0.4)	1	0.39
Skin bacterial infection								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Skin infection								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Subcutaneous abscess								
Female	0				0			
Male	0				1	(0.4)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tinea infection								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Tonsillitis								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Tooth abscess								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	2	(0.8)	2	0.77
Tooth infection								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Tracheitis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Upper respiratory tract infection								
Female	11	(5.6)	16	8.25	7	(3.1)	8	3.54
Male	12	(4.1)	14	4.80	6	(2.3)	6	2.32
Urethritis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Urinary tract infection								
Female	6	(3.0)	6	3.09	13	(5.7)	14	6.20
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Vaginal infection								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Varicella								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Viral infection								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	2	(0.8)	2	0.77
Viral pharyngitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Viral upper respiratory tract infection								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Vulvovaginal candidiasis								
Female	2	(1.0)	3	1.55	4	(1.7)	4	1.77
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal mycotic infection								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Injury, poisoning and procedural complications								
All								
Female	27	(13.7)	28	14.44	23	(10.0)	29	12.83
Male	33	(11.2)	37	12.67	17	(6.5)	23	8.88
Accidental overdose								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Animal bite								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Ankle fracture								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Arthropod sting								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Bone contusion								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Burn oral cavity								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Burns first degree								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Cervical vertebral fracture								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Chillblains								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Contusion								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	3	(1.0)	4	1.37	3	(1.1)	3	1.16
Deafness traumatic								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Endotracheal intubation complication								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.39
Eye injury								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Fall								
Female	3	(1.5)	3	1.55	0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Fibula fracture								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Foot fracture								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Hand fracture								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Heat illness								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	2	0.77
Hip fracture								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Injury								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Joint injury								
Female	0				0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Ligament sprain								
Female	2	(1.0)	2	1.03	0			
Male	0				1	(0.4)	1	0.39
Limb injury								
Female	2	(1.0)	2	1.03	0			
Male	1	(0.3)	1	0.34	0			
Lower limb fracture								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Meniscus injury								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Muscle strain								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
Overdose								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Post procedural fistula								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Post procedural haemorrhage								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Post procedural hypothyroidism								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Post procedural stroke								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Post procedural swelling								
Female	0				0			
Male	0				1	(0.4)	2	0.77
Procedural pain								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Radius fracture								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Rib fracture								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Scar								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Skin abrasion								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	0			
Skin laceration								
Female	0				0			
Male	3	(1.0)	3	1.03	0			
Soft tissue injury								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Thermal burn								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth fracture								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Traumatic haematoma								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Underdose								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Vaccination complication								
Female	3	(1.5)	3	1.55	10	(4.4)	14	6.20
Male	7	(2.4)	7	2.40	3	(1.1)	5	1.93
Wound								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Wrist fracture								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Investigations								
All								
Female	6	(3.0)	7	3.61	9	(3.9)	10	4.43
Male	15	(5.1)	17	5.82	12	(4.6)	12	4.63
Alanine aminotransferase increased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Aspartate aminotransferase increased								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Blood cholesterol increased								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Blood creatine increased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Blood creatine phosphokinase increased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Blood glucose increased								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Blood pressure decreased								

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.39
Blood pressure increased								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Blood triglycerides increased								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Body temperature increased								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Cardiac stress test abnormal								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Electrocardiogram repolarisation abnormality								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Glycosylated haemoglobin increased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Haemoglobin decreased								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hepatic enzyme increased								
Female	0				0			
Male	0				1	(0.4)	1	0.39
International normalised ratio abnormal								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
International normalised ratio decreased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
International normalised ratio increased								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Lipids increased								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Red blood cell count decreased								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
SARS-CoV-2 test positive								
Female	1	(0.5)	1	0.52	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
Transferrin saturation decreased								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Weight decreased								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Weight increased								
Female	1	(0.5)	1	0.52	4	(1.7)	4	1.77
Male	4	(1.4)	4	1.37	6	(2.3)	6	2.32
Metabolism and nutrition disorders								
All								
Female	16	(8.1)	19	9.80	21	(9.2)	32	14.16
Male	25	(8.5)	28	9.59	25	(9.5)	28	10.81
Appetite disorder								
Female	0				0			
Male	0				1	(0.4)	2	0.77
Decreased appetite								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Dehydration								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Diabetes mellitus								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Dyslipidaemia								
Female	4	(2.0)	4	2.06	4	(1.7)	4	1.77
Male	6	(2.0)	6	2.06	2	(0.8)	2	0.77
Electrolyte imbalance								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Fluid retention								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Gout								
Female	0				0			
Male	1	(0.3)	2	0.69	3	(1.1)	3	1.16
Hypercholesterolaemia								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperglycaemia								
Female	0				4	(1.7)	4	1.77
Male	0				2	(0.8)	2	0.77
Hyperkalaemia								
Female	2	(1.0)	3	1.55	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Hyperlipidaemia								
Female	1	(0.5)	1	0.52	0			
Male	3	(1.0)	3	1.03	3	(1.1)	3	1.16
Hypertriglyceridaemia								
Female	2	(1.0)	2	1.03	0			
Male	4	(1.4)	4	1.37	4	(1.5)	4	1.54
Hyperuricaemia								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Hypoglycaemia								
Female	1	(0.5)	2	1.03	5	(2.2)	15	6.64
Male	3	(1.0)	3	1.03	4	(1.5)	5	1.93
Hypokalaemia								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Increased appetite								
Female	0				1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Iron deficiency								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Malnutrition								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Metabolic disorder								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Obesity								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Vitamin D deficiency								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Zinc deficiency								
Female	1	(0.5)	1	0.52	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders								
All								
Female	43	(21.8)	74	38.16	53	(23.1)	79	34.96
Male	56	(19.0)	82	28.09	39	(14.8)	54	20.84
Arthralgia								
Female	15	(7.6)	17	8.77	11	(4.8)	12	5.31
Male	8	(2.7)	10	3.43	6	(2.3)	7	2.70
Arthritis								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Axillary mass								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Back disorder								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Back pain								
Female	10	(5.1)	11	5.67	10	(4.4)	11	4.87
Male	17	(5.8)	18	6.17	14	(5.3)	14	5.40
Bone cyst								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Bursitis								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	0				1	(0.4)	1	0.39
Cervical spinal stenosis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Chondropathy								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Coccydynia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Costochondritis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Dupuytren's contracture								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Exostosis								
Female	1	(0.5)	1	0.52	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.4)	1	0.39
Fibromyalgia								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Fistula								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Flank pain								
Female	0				1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Groin pain								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Intervertebral disc disorder								
Female	0				0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Intervertebral disc protrusion								
Female	0				2	(0.9)	3	1.33
Male	4	(1.4)	5	1.71	1	(0.4)	1	0.39
Joint effusion								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Joint swelling								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Limb deformity								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Lumbar spinal stenosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Mastication disorder								
Female	0				1	(0.4)	2	0.89
Male	0				0			
Muscle contracture								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Muscle spasms								
Female	5	(2.5)	5	2.58	2	(0.9)	2	0.89
Male	3	(1.0)	3	1.03	2	(0.8)	2	0.77
Muscular weakness								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal chest pain								
Female	0				0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Musculoskeletal pain								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Musculoskeletal stiffness								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Myalgia								
Female	0				1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39
Myositis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Neck pain								
Female	4	(2.0)	4	2.06	6	(2.6)	6	2.66
Male	2	(0.7)	2	0.69	0			
Osteoarthritis								
Female	8	(4.1)	10	5.16	6	(2.6)	7	3.10
Male	4	(1.4)	4	1.37	3	(1.1)	3	1.16
Osteochondrosis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Osteopenia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Pain in extremity								
Female	6	(3.0)	7	3.61	4	(1.7)	5	2.21
Male	9	(3.1)	9	3.08	7	(2.7)	9	3.47
Periarthritis								
Female	0				3	(1.3)	3	1.33
Male	6	(2.0)	6	2.06	1	(0.4)	1	0.39
Plantar fasciitis								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	3	1.03	1	(0.4)	1	0.39
Polyarthritis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Rotator cuff syndrome								
Female	2	(1.0)	2	1.03	0			
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal osteoarthritis								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Spinal pain								
Female	0				3	(1.3)	3	1.33
Male	1	(0.3)	1	0.34	0			
Spinal stenosis								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Synovial cyst								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Tendonitis								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77
Tenosynovitis								
Female	1	(0.5)	1	0.52	4	(1.7)	4	1.77
Male	0				1	(0.4)	2	0.77
Tenosynovitis stenosans								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Trigger finger								
Female	1	(0.5)	1	0.52	1	(0.4)	3	1.33
Male	0				1	(0.4)	1	0.39
Vertebral osteophyte								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	4	(2.0)	4	2.06	2	(0.9)	4	1.77
Male	7	(2.4)	9	3.08	3	(1.1)	5	1.93
Acrochordon								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Basal cell carcinoma								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Colon cancer								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Dysplastic naevus								

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.39
Glioblastoma multiforme								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Haemangioma of liver								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Hepatocellular carcinoma								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Malignant melanoma in situ								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Metastases to liver								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Neoplasm skin								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Oral fibroma								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Ovarian cancer metastatic								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Pancreatic neoplasm								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Prostate cancer								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Renal cell carcinoma								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Salivary gland neoplasm								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Seborrhoeic keratosis								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	2	0.69	0			
Uterine leiomyoma								
Female	0				1	(0.4)	1	0.44

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
Nervous system disorders								
All								
Female	30	(15.2)	41	21.14	35	(15.3)	41	18.14
Male	35	(11.9)	46	15.76	32	(12.2)	44	16.98
Ageusia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Anosmia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Balance disorder								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Brain injury								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Burning sensation								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Carotid arteriosclerosis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Carpal tunnel syndrome								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39
Cerebral atrophy								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Cerebral haemorrhage								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Cerebrovascular disorder								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Cervical radiculopathy								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Diabetic neuropathy								
Female	1	(0.5)	1	0.52	0			
Male	0				3	(1.1)	3	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dizziness								
Female	4	(2.0)	6	3.09	7	(3.1)	8	3.54
Male	8	(2.7)	10	3.43	7	(2.7)	7	2.70
Dizziness postural								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Dysgeusia								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Headache								
Female	10	(5.1)	12	6.19	10	(4.4)	10	4.43
Male	6	(2.0)	6	2.06	7	(2.7)	14	5.40
Hypoaesthesia								
Female	2	(1.0)	2	1.03	3	(1.3)	4	1.77
Male	3	(1.0)	5	1.71	0			
Lethargy								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Lumbar radiculopathy								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77
Memory impairment								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Mental impairment								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Migraine								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Neuralgia								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Neuroglycopenia								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	3	1.16
Neuropathy peripheral								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Paraesthesia								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Parkinsonian gait								

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Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.39
Post herpetic neuralgia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Presyncope								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			
Sciatica								
Female	2	(1.0)	2	1.03	3	(1.3)	4	1.77
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Somnolence								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Syncope								
Female	3	(1.5)	3	1.55	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Tension headache								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	2	0.69	0			
Thrombotic stroke								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Transient ischaemic attack								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Tremor								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	4	(1.4)	5	1.71	0			
Trigeminal neuralgia								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Vertebral artery occlusion								
Female	0				1	(0.4)	1	0.44
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Female	3	(1.5)	3	1.55	8	(3.5)	8	3.54
Male	12	(4.1)	13	4.45	2	(0.8)	2	0.77
Anxiety								
Female	0				2	(0.9)	2	0.89
Male	3	(1.0)	3	1.03	0			
Bruxism								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Depressed mood								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Depression								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Insomnia								
Female	2	(1.0)	2	1.03	3	(1.3)	3	1.33
Male	4	(1.4)	4	1.37	0			
Mood swings								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Nightmare								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Persistent depressive disorder								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Sleep disorder								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Renal and urinary disorders								
All								
Female	8	(4.1)	10	5.16	6	(2.6)	6	2.66
Male	6	(2.0)	8	2.74	14	(5.3)	16	6.18
Acute kidney injury								
Female	0				0			
Male	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Chronic kidney disease								
Female	1	(0.5)	1	0.52	0			
Male	0				2	(0.8)	2	0.77
Diabetic nephropathy								
Female	2	(1.0)	2	1.03	0			
Male	0				0			
Dysuria								
Female	0				0			
Male	1	(0.3)	1	0.34	3	(1.1)	3	1.16
Haematuria								
Female	0				1	(0.4)	1	0.44
Male	0				2	(0.8)	2	0.77
Microalbuminuria								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Nephrolithiasis								
Female	0				0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Nocturia								
Female	1	(0.5)	1	0.52	0			
Male	0				2	(0.8)	2	0.77
Pollakiuria								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				1	(0.4)	1	0.39
Pyelocaliectasis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Renal colic								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Renal cyst								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Renal impairment								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	2	(0.8)	2	0.77
Ureterolithiasis								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urinary incontinence								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Urinary retention								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Urinary tract obstruction								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Urine odour abnormal								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Reproductive system and breast disorders								
All								
Female	6	(3.0)	6	3.09	5	(2.2)	6	2.66
Male	4	(1.4)	4	1.37	2	(0.8)	3	1.16
Atrophic vulvovaginitis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Benign prostatic hyperplasia								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Breast mass								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Breast pain								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Erectile dysfunction								
Female	0				0			
Male	2	(0.7)	2	0.69	0			
Galactorrhoea								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Menopausal symptoms								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Ovarian cyst								
Female	1	(0.5)	1	0.52	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Penile rash								
Female	0				0			
Male	0				1	(0.4)	2	0.77
Pruritus genital								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Uterine polyp								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Uterine prolapse								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Vulvovaginal dryness								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Vulvovaginal pruritus								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Female	16	(8.1)	18	9.28	20	(8.7)	23	10.18
Male	29	(9.8)	41	14.04	18	(6.8)	29	11.19
Acquired diaphragmatic eventration								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Acute pulmonary oedema								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Acute respiratory failure								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Allergic bronchitis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Asthma								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Bronchiectasis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis chronic								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Chronic obstructive pulmonary disease								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Cough								
Female	3	(1.5)	3	1.55	3	(1.3)	3	1.33
Male	7	(2.4)	7	2.40	5	(1.9)	6	2.32
Dyspnoea								
Female	0				3	(1.3)	3	1.33
Male	0				2	(0.8)	2	0.77
Dyspnoea exertional								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Emphysema								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Epistaxis								
Female	0				1	(0.4)	2	0.89
Male	0				0			
Haemoptysis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Interstitial lung disease								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Laryngeal cyst								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Nasal congestion								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	1	(0.4)	1	0.39
Nasal dryness								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Nasal turbinate hypertrophy								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Oropharyngeal pain								
Female	4	(2.0)	4	2.06	4	(1.7)	4	1.77
Male	6	(2.0)	7	2.40	3	(1.1)	4	1.54

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paranasal sinus discomfort								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Pleural effusion								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Pleuritic pain								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Productive cough								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Pulmonary embolism								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Pulmonary fibrosis								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Pulmonary mass								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Respiratory disorder								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	0				1	(0.4)	1	0.39
Respiratory failure								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Rhinitis allergic								
Female	0				0			
Male	0				1	(0.4)	5	1.93
Rhinorrhoea								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	2	(0.8)	2	0.77
Sinus congestion								
Female	0				0			
Male	1	(0.3)	2	0.69	1	(0.4)	1	0.39
Sinus pain								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Sleep apnoea syndrome								
Female	0				0			
Male	3	(1.0)	3	1.03	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sneezing								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Throat irritation								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Upper-airway cough syndrome								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Skin and subcutaneous tissue disorders								
All								
Female	15	(7.6)	16	8.25	26	(11.4)	35	15.49
Male	27	(9.2)	28	9.59	16	(6.1)	20	7.72
Actinic keratosis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Alopecia								
Female	2	(1.0)	2	1.03	2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			
Alopecia areata								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Angioedema								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Asteatosis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Blister								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Cold sweat								
Female	1	(0.5)	1	0.52	2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			
Cold urticaria								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Dermal cyst								
Female	0				2	(0.9)	2	0.89
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Dermatitis allergic								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Dermatitis contact								
Female	2	(1.0)	3	1.55	4	(1.7)	4	1.77
Male	3	(1.0)	3	1.03	2	(0.8)	2	0.77
Diabetic foot								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Drug eruption								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Dry skin								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	0			
Ecchymosis								
Female	0				2	(0.9)	2	0.89
Male	0				0			
Eczema								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	3	(1.0)	3	1.03	0			
Erythema								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Granuloma annulare								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Haemorrhage subcutaneous								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hyperhidrosis								
Female	0				1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Hyperkeratosis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Ingrowing nail								
Female	0				2	(0.9)	2	0.89
Male	1	(0.3)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lentigo								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Lipodystrophy acquired								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Lipohypertrophy								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Macule								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Miliaria								
Female	0				2	(0.9)	2	0.89
Male	0				2	(0.8)	2	0.77
Myxoid cyst								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Night sweats								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Pruritus								
Female	0				2	(0.9)	2	0.89
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Psoriasis								
Female	1	(0.5)	1	0.52	0			
Male	1	(0.3)	1	0.34	0			
Purpura								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Rash								
Female	0				3	(1.3)	3	1.33
Male	2	(0.7)	2	0.69	3	(1.1)	3	1.16
Skin exfoliation								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Skin fissures								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Skin irritation								
Female	0				0			
Male	2	(0.7)	3	1.03	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin lesion								
Female	1	(0.5)	1	0.52	0			
Male	0				1	(0.4)	1	0.39
Skin ulcer								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Urticaria								
Female	0				3	(1.3)	3	1.33
Male	0				1	(0.4)	1	0.39
Urticaria contact								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Urticaria thermal								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Surgical and medical procedures								
All								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39
Knee operation								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Large intestinal polypectomy								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Removal of foreign body								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Vascular disorders								
All								
Female	12	(6.1)	14	7.22	8	(3.5)	10	4.43
Male	20	(6.8)	23	7.88	17	(6.5)	19	7.33
Aortic arteriosclerosis								
Female	0				1	(0.4)	1	0.44
Male	2	(0.7)	2	0.69	0			
Aortic stenosis								
Female	1	(0.5)	1	0.52	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
Female	1	(0.5)	1	0.52	0			
Male	0				2	(0.8)	2	0.77
Blood pressure inadequately controlled								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Brachiocephalic arteriosclerosis								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				2	(0.8)	2	0.77
Flushing								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Haematoma								
Female	1	(0.5)	1	0.52	1	(0.4)	1	0.44
Male	0				0			
Hypertension								
Female	4	(2.0)	4	2.06	2	(0.9)	2	0.89
Male	9	(3.1)	9	3.08	8	(3.0)	9	3.47
Hypertensive crisis								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Hypertensive urgency								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Hypotension								
Female	1	(0.5)	1	0.52	0			
Male	2	(0.7)	2	0.69	1	(0.4)	1	0.39
Iliac artery stenosis								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Intermittent claudication								
Female	0				0			
Male	0				1	(0.4)	1	0.39
Macroangiopathy								
Female	0				1	(0.4)	1	0.44
Male	0				0			
Peripheral arterial occlusive disease								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	2	0.69	1	(0.4)	1	0.39
Peripheral artery occlusion								
Female	1	(0.5)	1	0.52	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
Female	0				0			
Male	1	(0.3)	2	0.69	0			
Peripheral coldness								
Female	2	(1.0)	2	1.03	1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Peripheral vascular disorder								
Female	1	(0.5)	1	0.52	0			
Male	0				0			
Peripheral venous disease								
Female	0				1	(0.4)	1	0.44
Male	1	(0.3)	1	0.34	0			
Superficial vein thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.34	0			
Varicose vein								
Female	0				0			
Male	1	(0.3)	1	0.34	1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:10:43 - taesocptgrptrl/taesocptgrpsexsumontowlsas.txt

7.16.6 Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	101				123			
Male	161				140			
PYE (years)								
Female	59.80				70.42			
Male	95.44				82.35			
Events								
Female	63	(62.4)	211	352.83	62	(50.4)	146	207.33
Male	98	(60.9)	255	267.17	72	(51.4)	182	221.00
Blood and lymphatic system disorders								
All								
Female	1	(1.0)	3	5.02	1	(0.8)	1	1.42
Male	0				0			
Anaemia								
Female	1	(1.0)	3	5.02	0			
Male	0				0			
Thrombocytosis								
Female	0				1	(0.8)	1	1.42
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Female	1	(1.0)	1	1.67	0			
Male	4	(2.5)	6	6.29	2	(1.4)	2	2.43
Acute myocardial infarction								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Atrial fibrillation								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Bradycardia								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Cardiac failure congestive								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Cardiac flutter								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Coronary artery disease								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Myocardial infarction								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Supraventricular tachycardia								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Female	1	(1.0)	1	1.67	2	(1.6)	2	2.84
Male	3	(1.9)	3	3.14	2	(1.4)	2	2.43
Deafness unilateral								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Ear pain								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Hypoacusis								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tinnitus								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Vertigo								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Endocrine disorders								
All								
Female	0				3	(2.4)	3	4.26
Male	0				0			
Adrenocortical insufficiency acute								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Hypothyroidism								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Inappropriate antidiuretic hormone secretion								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Eye disorders								
All								
Female	8	(7.9)	8	13.38	10	(8.1)	10	14.20
Male	19	(11.8)	23	24.10	15	(10.7)	20	24.29
Astigmatism								
Female	0				0			
Male	0				1	(0.7)	1	1.21

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
Female	0				3	(2.4)	3	4.26
Male	2	(1.2)	2	2.10	1	(0.7)	1	1.21
Cataract nuclear								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Conjunctival haemorrhage								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Diabetic retinal oedema								
Female	0				1	(0.8)	1	1.42
Male	2	(1.2)	2	2.10	1	(0.7)	1	1.21
Diabetic retinopathy								
Female	1	(1.0)	1	1.67	5	(4.1)	5	7.10
Male	9	(5.6)	10	10.48	11	(7.9)	12	14.57
Dry age-related macular degeneration								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Dry eye								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Epiretinal membrane								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Eye irritation								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Glaucoma								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Lacrimation increased								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Macular oedema								
Female	0				0			
Male	2	(1.2)	2	2.10	0			
Myopia								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Non-proliferative retinopathy								
Female	0				0			
Male	0				1	(0.7)	1	1.21

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ocular hyperaemia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Ocular hypertension								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Presbyopia								
Female	0				0			
Male	0				2	(1.4)	2	2.43
Retinal exudates								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Retinal haemorrhage								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Retinal vein occlusion								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Vision blurred								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Visual acuity reduced								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Vitreous haemorrhage								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Gastrointestinal disorders								
All								
Female	18	(17.8)	31	51.84	14	(11.4)	19	26.98
Male	20	(12.4)	29	30.38	18	(12.9)	23	27.93
Abdominal pain								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Abdominal pain lower								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Abdominal pain upper								
Female	1	(1.0)	3	5.02	2	(1.6)	2	2.84
Male	0				1	(0.7)	1	1.21
Chronic gastritis								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Constipation								
Female	3	(3.0)	4	6.69	0			
Male	1	(0.6)	3	3.14	0			
Dental caries								
Female	0				1	(0.8)	1	1.42
Male	0				1	(0.7)	1	1.21
Diarrhoea								
Female	6	(5.9)	6	10.03	3	(2.4)	3	4.26
Male	8	(5.0)	11	11.53	6	(4.3)	6	7.29
Diverticulum								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Dyspepsia								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	2	(1.2)	2	2.10	0			
Flatulence								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Food poisoning								
Female	0				1	(0.8)	2	2.84
Male	1	(0.6)	1	1.05	0			
Gastric dysplasia								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Gastric mucosal hypertrophy								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Gastric polyps								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Gastritis								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Gastrointestinal angiodysplasia								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Gastrooesophageal reflux disease								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Gingival bleeding								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Haemorrhoids								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42

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Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.7)	1	1.21
Hiatus hernia								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Hyperaesthesia teeth								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Intra-abdominal haematoma								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Large intestine polyp								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Nausea								
Female	6	(5.9)	6	10.03	2	(1.6)	2	2.84
Male	1	(0.6)	1	1.05	4	(2.9)	4	4.86
Pancreatic pseudocyst								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Periodontal disease								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Tongue rough								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Toothache								
Female	0				1	(0.8)	3	4.26
Male	1	(0.6)	1	1.05	2	(1.4)	2	2.43
Vomiting								
Female	1	(1.0)	1	1.67	0			
Male	2	(1.2)	2	2.10	3	(2.1)	3	3.64
General disorders and administration site conditions								
All								
Female	10	(9.9)	15	25.08	8	(6.5)	8	11.36
Male	15	(9.3)	21	22.00	11	(7.9)	13	15.79
Asthenia								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Chest discomfort								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Chest pain								

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Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Chills								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Condition aggravated								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Fatigue								
Female	2	(2.0)	3	5.02	2	(1.6)	2	2.84
Male	0				1	(0.7)	1	1.21
Hunger								
Female	1	(1.0)	1	1.67	0			
Male	0				1	(0.7)	1	1.21
Influenza like illness								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Injection site reaction								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Injection site swelling								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Malaise								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	1	(0.7)	2	2.43
Medical device site bruise								
Female	0				0			
Male	1	(0.6)	2	2.10	0			
Medical device site dermatitis								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Medical device site erythema								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Medical device site pruritus								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Medical device site rash								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Medical device site reaction								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oedema peripheral								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Pain								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Pyrexia								
Female	3	(3.0)	3	5.02	3	(2.4)	3	4.26
Male	3	(1.9)	3	3.14	3	(2.1)	3	3.64
Vaccination site pain								
Female	1	(1.0)	1	1.67	0			
Male	2	(1.2)	3	3.14	3	(2.1)	3	3.64
Hepatobiliary disorders								
All								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Alcoholic liver disease								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Gallbladder polyp								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Hepatic cirrhosis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Immune system disorders								
All								
Female	1	(1.0)	1	1.67	3	(2.4)	3	4.26
Male	1	(0.6)	1	1.05	2	(1.4)	2	2.43
Allergy to arthropod bite								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Allergy to arthropod sting								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Anaphylactic reaction								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Seasonal allergy								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				1	(0.7)	1	1.21

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infections and infestations								
All								
Female	29	(28.7)	39	65.21	25	(20.3)	34	48.28
Male	47	(29.2)	59	61.82	24	(17.1)	32	38.86
Abscess limb								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			
Anal abscess								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Bronchitis								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Campylobacter gastroenteritis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Cellulitis								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	2	2.43
Conjunctivitis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
COVID-19								
Female	3	(3.0)	3	5.02	3	(2.4)	3	4.26
Male	6	(3.7)	6	6.29	4	(2.9)	4	4.86
COVID-19 pneumonia								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Cystitis								
Female	1	(1.0)	1	1.67	2	(1.6)	3	4.26
Male	0				0			
Ear infection								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			
Enteritis infectious								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Eye infection								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Folliculitis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Fungal infection								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	1	(1.0)	2	3.34	0			
Male	0				0			
Fungal skin infection								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Gastroenteritis								
Female	3	(3.0)	3	5.02	2	(1.6)	2	2.84
Male	2	(1.2)	2	2.10	0			
Gastrointestinal infection								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Gingivitis								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Helicobacter infection								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Herpes zoster								
Female	0				1	(0.8)	1	1.42
Male	0				2	(1.4)	2	2.43
Influenza								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	3	(2.1)	4	4.86
Kidney infection								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Localised infection								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Nasopharyngitis								
Female	8	(7.9)	8	13.38	4	(3.3)	6	8.52
Male	14	(8.7)	20	20.95	6	(4.3)	8	9.71
Onychomycosis								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Otitis media								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	2	(1.2)	2	2.10	0			
Paraspinal abscess								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Peritonsillar abscess								
Female	0				0			
Male	0				1	(0.7)	1	1.21

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumonia								
Female	0				0			
Male	2	(1.2)	2	2.10	0			
Pulpitis dental								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Pustule								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Rhinitis								
Female	0				1	(0.8)	3	4.26
Male	0				0			
Sinusitis								
Female	1	(1.0)	1	1.67	2	(1.6)	2	2.84
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Soft tissue infection								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Subcutaneous abscess								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tinea pedis								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Tinea versicolour								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tonsillitis								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Tooth abscess								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tooth infection								
Female	1	(1.0)	2	3.34	1	(0.8)	1	1.42
Male	0				2	(1.4)	2	2.43
Upper respiratory tract infection								
Female	4	(4.0)	5	8.36	2	(1.6)	2	2.84
Male	4	(2.5)	6	6.29	2	(1.4)	2	2.43
Urinary tract infection								
Female	2	(2.0)	2	3.34	2	(1.6)	2	2.84
Male	2	(1.2)	3	3.14	1	(0.7)	1	1.21
Vaginal infection								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella zoster virus infection								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Vulvitis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Vulvovaginal candidiasis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Wound infection								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Injury, poisoning and procedural complications								
All								
Female	11	(10.9)	19	31.77	9	(7.3)	9	12.78
Male	16	(9.9)	20	20.95	13	(9.3)	17	20.64
Accidental overdose								
Female	2	(2.0)	2	3.34	0			
Male	2	(1.2)	2	2.10	0			
Arthropod bite								
Female	1	(1.0)	1	1.67	0			
Male	0				1	(0.7)	1	1.21
Arthropod sting								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Bone contusion								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Contusion								
Female	0				0			
Male	2	(1.2)	2	2.10	0			
Craniocerebral injury								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Face injury								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Facial bones fracture								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Fall								
Female	3	(3.0)	3	5.02	2	(1.6)	2	2.84

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	2	(1.2)	2	2.10	0			
Foot fracture								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Hand fracture								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Heat illness								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Intentional overdose								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Joint injury								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Ligament sprain								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	0			
Limb injury								
Female	0				0			
Male	0				1	(0.7)	2	2.43
Muscle contusion								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Muscle injury								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Overdose								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Rib fracture								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Road traffic accident								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Skin abrasion								
Female	0				0			
Male	2	(1.2)	2	2.10	1	(0.7)	1	1.21
Skin laceration								
Female	0				0			
Male	2	(1.2)	2	2.10	0			
Stab wound								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.7)	1	1.21
Subcutaneous haematoma								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Tendon injury								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Tendon rupture								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Thermal burn								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tibia fracture								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Underdose								
Female	1	(1.0)	1	1.67	2	(1.6)	2	2.84
Male	0				1	(0.7)	1	1.21
Vaccination complication								
Female	3	(3.0)	7	11.71	0			
Male	1	(0.6)	1	1.05	3	(2.1)	3	3.64
Wound								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Wrist fracture								
Female	0				0			
Male	1	(0.6)	1	1.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
Female	2	(2.0)	2	3.34	2	(1.6)	2	2.84
Male	3	(1.9)	3	3.14	1	(0.7)	2	2.43
Alanine aminotransferase increased								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Blood creatinine increased								
Female	1	(1.0)	1	1.67	0			
Male	2	(1.2)	2	2.10	0			
Blood potassium increased								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Intraocular pressure increased								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Liver function test abnormal								
Female	0				0			
Male	0				1	(0.7)	2	2.43
SARS-CoV-2 test positive								
Female	0				0			
Male	1	(0.6)	1	1.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Female	3	(3.0)	3	5.02	6	(4.9)	7	9.94
Male	4	(2.5)	4	4.19	5	(3.6)	9	10.93
Abnormal weight gain								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Hyperammonaemia								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Hypercholesterolaemia								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Hyperglycaemia								
Female	0				2	(1.6)	2	2.84
Male	2	(1.2)	2	2.10	0			
Hyperkalaemia								
Female	1	(1.0)	1	1.67	0			
Male	0				1	(0.7)	1	1.21
Hyperlipidaemia								
Female	0				1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	2	(1.4)	2	2.43
Hyperuricaemia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Hypoglycaemia								
Female	1	(1.0)	1	1.67	2	(1.6)	3	4.26
Male	0				1	(0.7)	5	6.07
Musculoskeletal and connective tissue disorders								
All								
Female	20	(19.8)	31	51.84	13	(10.6)	22	31.24
Male	18	(11.2)	29	30.38	16	(11.4)	23	27.93
Arthralgia								
Female	4	(4.0)	5	8.36	4	(3.3)	5	7.10
Male	2	(1.2)	2	2.10	6	(4.3)	8	9.71
Arthritis								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				1	(0.7)	1	1.21
Axillary mass								
Female	0				0			
Male	1	(0.6)	1	1.05	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Back pain								
Female	5	(5.0)	5	8.36	6	(4.9)	7	9.94
Male	2	(1.2)	2	2.10	5	(3.6)	6	7.29
Bursitis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Flank pain								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			
Intervertebral disc disorder								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Intervertebral disc protrusion								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Muscle spasms								
Female	2	(2.0)	2	3.34	0			
Male	7	(4.3)	9	9.43	1	(0.7)	1	1.21
Musculoskeletal stiffness								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Myalgia								
Female	2	(2.0)	2	3.34	1	(0.8)	1	1.42
Male	2	(1.2)	2	2.10	1	(0.7)	1	1.21
Neck pain								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Osteoarthritis								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Osteoporosis								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Pain in extremity								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	2	(1.2)	2	2.10	4	(2.9)	5	6.07
Periarthritis								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Plantar fasciitis								
Female	0				0			
Male	1	(0.6)	1	1.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Polymyalgia rheumatica								
Female	1	(1.0)	1	1.67	1	(0.8)	3	4.26
Male	0				0			
Rheumatoid arthritis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Rotator cuff syndrome								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Soft tissue swelling								
Female	1	(1.0)	3	5.02	0			
Male	0				0			
Spinal stenosis								
Female	1	(1.0)	2	3.34	0			
Male	1	(0.6)	2	2.10	0			
Tendonitis								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	3	3.14	0			
Tenosynovitis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Trigger finger								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	1	(1.0)	1	1.67	3	(2.4)	3	4.26
Male	2	(1.2)	2	2.10	1	(0.7)	1	1.21
Breast cancer								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Chronic myeloid leukaemia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Colon adenoma								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Colon cancer stage II								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Gastric cancer								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Lymphangioma								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Pancreatic carcinoma metastatic								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Nervous system disorders								
All								
Female	18	(17.8)	27	45.15	8	(6.5)	12	17.04
Male	9	(5.6)	15	15.72	17	(12.1)	22	26.71
Autonomic nervous system imbalance								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Burning sensation								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Carotid artery aneurysm								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Carpal tunnel syndrome								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cerebral infarction								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Cervicobrachial syndrome								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Diabetic neuropathy								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Dizziness								
Female	2	(2.0)	3	5.02	4	(3.3)	4	5.68
Male	2	(1.2)	2	2.10	5	(3.6)	9	10.93
Facial paralysis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Headache								
Female	9	(8.9)	13	21.74	3	(2.4)	4	5.68
Male	5	(3.1)	7	7.33	6	(4.3)	6	7.29
Hypoaesthesia								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Migraine								
Female	2	(2.0)	2	3.34	0			
Male	0				0			
Neuralgia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Neuropathy peripheral								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Peripheral paralysis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Piriformis syndrome								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Post herpetic neuralgia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Restless legs syndrome								
Female	0				0			
Male	0				1	(0.7)	1	1.21

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sciatica								
Female	2	(2.0)	2	3.34	0			
Male	0				2	(1.4)	2	2.43
Somnolence								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Syncope								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Tension headache								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Thalamic infarction								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Thrombotic stroke								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Tremor								
Female	0				1	(0.8)	1	1.42
Male	0				1	(0.7)	1	1.21
Psychiatric disorders								
All								
Female	3	(3.0)	4	6.69	1	(0.8)	1	1.42
Male	1	(0.6)	1	1.05	4	(2.9)	4	4.86
Adjustment disorder								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Depression								
Female	1	(1.0)	1	1.67	0			
Male	0				2	(1.4)	2	2.43
Insomnia								
Female	2	(2.0)	2	3.34	0			
Male	1	(0.6)	1	1.05	0			
Major depression								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Sleep disorder								
Female	0				0			
Male	0				2	(1.4)	2	2.43

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Female	6	(5.9)	8	13.38	0			
Male	2	(1.2)	2	2.10	0			
Bladder prolapse								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Diabetic nephropathy								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Hydronephrosis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Nephrotic syndrome								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Pollakiuria								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Polyuria								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Renal cyst								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Renal impairment								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Urethral stenosis								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Urine odour abnormal								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	3	(1.9)	3	3.14	1	(0.7)	1	1.21
Benign prostatic hyperplasia								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Cervical polyp								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Erectile dysfunction								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Prostatitis								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Pruritus genital								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Female	3	(3.0)	7	11.71	1	(0.8)	2	2.84
Male	12	(7.5)	22	23.05	3	(2.1)	3	3.64
Acute respiratory failure								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Chronic obstructive pulmonary disease								
Female	0				0			
Male	2	(1.2)	2	2.10	0			
Cough								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	2	2.10	0			
Epistaxis								
Female	1	(1.0)	1	1.67	0			
Male	2	(1.2)	6	6.29	0			
Nasal congestion								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Nasal obstruction								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal septum deviation								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Oropharyngeal pain								
Female	1	(1.0)	1	1.67	1	(0.8)	2	2.84
Male	0				1	(0.7)	1	1.21
Productive cough								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Respiratory failure								
Female	0				0			
Male	1	(0.6)	1	1.05	0			
Rhinorrhoea								
Female	1	(1.0)	1	1.67	0			
Male	4	(2.5)	6	6.29	1	(0.7)	1	1.21
Sleep apnoea syndrome								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Sneezing								
Female	0				0			
Male	1	(0.6)	1	1.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
Female	6	(5.9)	6	10.03	4	(3.3)	4	5.68
Male	7	(4.3)	8	8.38	2	(1.4)	2	2.43
Alopecia								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Blister								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Dermal cyst								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Dermatitis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Eczema								
Female	0				0			
Male	1	(0.6)	1	1.05	1	(0.7)	1	1.21
Hyperhidrosis								
Female	1	(1.0)	1	1.67	1	(0.8)	1	1.42
Male	0				0			
Miliaria								
Female	1	(1.0)	1	1.67	0			
Male	1	(0.6)	1	1.05	0			
Neurodermatitis								
Female	0				1	(0.8)	1	1.42
Male	0				0			
Pruritus								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Rash								
Female	0				1	(0.8)	1	1.42
Male	3	(1.9)	3	3.14	0			
Rash papular								
Female	1	(1.0)	1	1.67	0			
Male	0				0			
Urticaria								
Female	0				0			
Male	3	(1.9)	3	3.14	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Toe amputation								
Female	0				0			
Male	0				1	(0.7)	1	1.21
Vascular disorders								
All								
Female	2	(2.0)	2	3.34	2	(1.6)	2	2.84
Male	3	(1.9)	3	3.14	3	(2.1)	3	3.64
Hypertension								
Female	1	(1.0)	1	1.67	2	(1.6)	2	2.84
Male	3	(1.9)	3	3.14	3	(2.1)	3	3.64
Orthostatic hypotension								
Female	1	(1.0)	1	1.67	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

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7.16.7 Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	137				141			
Male	154				150			
PYE (years)								
Female	79.05				80.56			
Male	88.31				86.23			
Events								
Female	86	(62.8)	209	264.38	80	(56.7)	304	377.34
Male	85	(55.2)	246	278.57	87	(58.0)	246	285.27
Blood and lymphatic system disorders								
All								
Female	4	(2.9)	4	5.06	3	(2.1)	3	3.72
Male	3	(1.9)	3	3.40	2	(1.3)	2	2.32
Anaemia								
Female	3	(2.2)	3	3.79	2	(1.4)	2	2.48
Male	0				1	(0.7)	1	1.16
Blood loss anaemia								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Eosinophilia								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Iron deficiency anaemia								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Lymphadenopathy mediastinal								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Cardiac disorders								
All								
Female	2	(1.5)	2	2.53	8	(5.7)	15	18.62
Male	5	(3.2)	6	6.79	6	(4.0)	7	8.12
Acute myocardial infarction								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Angina pectoris								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Aortic valve calcification								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Aortic valve sclerosis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Atrial enlargement								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Atrial fibrillation								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Bundle branch block left								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Bundle branch block right								
Female	0				1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Cardiac failure								
Female	0				1	(0.7)	2	2.48
Male	0				0			
Cardiac failure congestive								
Female	0				0			
Male	0				2	(1.3)	3	3.48
Cardiac perfusion defect								
Female	0				1	(0.7)	2	2.48
Male	0				0			
Coronary artery disease								
Female	0				2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
Left atrial enlargement								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Left ventricular hypertrophy								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Myocardial infarction								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Myocardial ischaemia								
Female	0				0			
Male	1	(0.6)	1	1.13	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Palpitations								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Pericarditis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Sinus bradycardia								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Tachycardia								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Congenital, familial and genetic disorders								
All								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Corneal dystrophy								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Ear and labyrinth disorders								
All								
Female	1	(0.7)	1	1.26	2	(1.4)	2	2.48
Male	0				3	(2.0)	3	3.48
Cerumen impaction								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Ear discomfort								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Middle ear inflammation								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Vertigo								
Female	0				2	(1.4)	2	2.48
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Female	0				1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	0			
Adrenocortical insufficiency acute								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Hypogonadism								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Hypothyroidism								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Eye disorders								
All								
Female	9	(6.6)	11	13.91	15	(10.6)	27	33.51
Male	17	(11.0)	22	24.91	23	(15.3)	30	34.79
Age-related macular degeneration								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Astigmatism								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Cataract								
Female	0				1	(0.7)	2	2.48
Male	2	(1.3)	2	2.26	3	(2.0)	4	4.64
Corneal erosion								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Diabetic retinal oedema								
Female	0				3	(2.1)	4	4.96
Male	2	(1.3)	2	2.26	0			
Diabetic retinopathy								
Female	4	(2.9)	4	5.06	6	(4.3)	6	7.45
Male	8	(5.2)	10	11.32	9	(6.0)	9	10.44
Diplopia								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Eye discharge								
Female	0				0			
Male	0				1	(0.7)	1	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye inflammation								
Female	0				0			
Male	0				2	(1.3)	2	2.32
Eye pain								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Macular degeneration								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Macular oedema								
Female	2	(1.5)	2	2.53	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Meibomianitis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Open angle glaucoma								
Female	0				0			
Male	0				1	(0.7)	2	2.32
Presbyopia								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Retinal deposits								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Retinal detachment								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Retinal drusen								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Retinal exudates								
Female	0				0			
Male	0				2	(1.3)	2	2.32
Retinal haemorrhage								
Female	0				0			
Male	2	(1.3)	2	2.26	0			
Retinal scar								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Retinal vascular disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Retinopathy hypertensive								
Female	2	(1.5)	2	2.53	0			
Male	0				4	(2.7)	4	4.64

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Visual impairment								
Female	0				1	(0.7)	9	11.17
Male	0				0			
Vitreous detachment								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Vitreous haemorrhage								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Gastrointestinal disorders								
All								
Female	16	(11.7)	20	25.30	14	(9.9)	22	27.31
Male	19	(12.3)	30	33.97	21	(14.0)	27	31.31
Abdominal discomfort								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	2	2.32
Abdominal distension								
Female	0				1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Abdominal pain								
Female	2	(1.5)	2	2.53	4	(2.8)	5	6.21
Male	0				1	(0.7)	1	1.16
Abdominal pain upper								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Chronic gastritis								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Constipation								
Female	2	(1.5)	2	2.53	0			
Male	0				3	(2.0)	3	3.48
Dental caries								
Female	0				0			
Male	0				4	(2.7)	4	4.64
Diarrhoea								
Female	5	(3.6)	5	6.32	6	(4.3)	6	7.45
Male	10	(6.5)	13	14.72	3	(2.0)	3	3.48
Eructation								
Female	0				0			
Male	0				1	(0.7)	1	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Faeces pale								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Food poisoning								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Gastrointestinal disorder								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Gastrointestinal haemorrhage								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Gastrooesophageal reflux disease								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Gingival disorder								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Hypoaesthesia oral								
Female	0				0			
Male	2	(1.3)	4	4.53	0			
Nausea								
Female	1	(0.7)	1	1.26	4	(2.8)	4	4.96
Male	4	(2.6)	4	4.53	0			
Pancreatic duct dilatation								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pancreatic failure								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pancreatitis chronic								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Periodontal disease								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Proctalgia								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Toothache								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	2	(1.3)	3	3.48
Upper gastrointestinal haemorrhage								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.7)	1	1.16
Vomiting								
Female	6	(4.4)	8	10.12	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
General disorders and administration site conditions								
All								
Female	16	(11.7)	24	30.36	11	(7.8)	18	22.34
Male	10	(6.5)	14	15.85	15	(10.0)	18	20.87
Asthenia								
Female	2	(1.5)	2	2.53	1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Axillary pain								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Chest pain								
Female	1	(0.7)	1	1.26	0			
Male	2	(1.3)	2	2.26	0			
Cyst								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Discomfort								
Female	0				1	(0.7)	8	9.93
Male	0				0			
Facial pain								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Fatigue								
Female	3	(2.2)	4	5.06	1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Feeling abnormal								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Inflammation								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Injection site pain								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Injection site rash								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Injection site reaction								

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Malaise								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	2	2.32
Medical device site dermatitis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Medical device site erythema								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Medical device site pain								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Medical device site reaction								
Female	2	(1.5)	2	2.53	0			
Male	0				0			
Multiple organ dysfunction syndrome								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Oedema								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Oedema due to renal disease								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Oedema peripheral								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	2	(1.3)	2	2.32
Pain								
Female	3	(2.2)	4	5.06	0			
Male	0				1	(0.7)	1	1.16
Peripheral swelling								
Female	0				2	(1.4)	2	2.48
Male	0				0			
Pyrexia								
Female	2	(1.5)	2	2.53	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	4	(2.7)	5	5.80
Thirst								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Vaccination site inflammation								
Female	1	(0.7)	1	1.26	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
Female	0				0			
Male	3	(1.9)	3	3.40	2	(1.3)	2	2.32
Vaccination site pruritus								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Xerosis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Hepatobiliary disorders								
All								
Female	0				3	(2.1)	3	3.72
Male	2	(1.3)	3	3.40	1	(0.7)	3	3.48
Biliary dyskinesia								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Cholecystitis chronic								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Gallbladder polyp								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Hepatic function abnormal								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Hepatic steatosis								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Hepatomegaly								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Hyperplastic cholecystopathy								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Liver disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Female	1	(0.7)	1	1.26	2	(1.4)	2	2.48
Male	2	(1.3)	2	2.26	0			
Drug hypersensitivity								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Hypersensitivity								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Seasonal allergy								
Female	0				2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
Infections and infestations								
All								
Female	46	(33.6)	58	73.37	41	(29.1)	72	89.37
Male	41	(26.6)	59	66.81	38	(25.3)	48	55.66
Abscess								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Asymptomatic COVID-19								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Bacteraemia								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Breast abscess								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Bronchitis								
Female	4	(2.9)	4	5.06	1	(0.7)	1	1.24
Male	4	(2.6)	4	4.53	2	(1.3)	2	2.32
Candida infection								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Cellulitis								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Cholecystitis infective								
Female	0				0			
Male	1	(0.6)	1	1.13	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctivitis								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Coronavirus infection								
Female	0				1	(0.7)	2	2.48
Male	0				0			
COVID-19								
Female	14	(10.2)	14	17.71	15	(10.6)	17	21.10
Male	12	(7.8)	12	13.59	8	(5.3)	8	9.28
COVID-19 pneumonia								
Female	2	(1.5)	2	2.53	0			
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Cystitis								
Female	2	(1.5)	2	2.53	3	(2.1)	3	3.72
Male	0				0			
Diabetic foot infection								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Eye infection								
Female	0				1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Fungal infection								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Fungal skin infection								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Gastroenteritis								
Female	4	(2.9)	4	5.06	4	(2.8)	5	6.21
Male	3	(1.9)	3	3.40	1	(0.7)	1	1.16
Gastroenteritis viral								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Gingivitis								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Herpes zoster								
Female	0				0			
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Infected dermal cyst								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Influenza								
Female	1	(0.7)	1	1.26	3	(2.1)	5	6.21
Male	4	(2.6)	4	4.53	5	(3.3)	5	5.80

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Localised infection								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Nasopharyngitis								
Female	5	(3.6)	5	6.32	5	(3.5)	7	8.69
Male	3	(1.9)	3	3.40	7	(4.7)	8	9.28
Oral herpes								
Female	1	(0.7)	2	2.53	0			
Male	0				0			
Osteomyelitis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Otitis media								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Otitis media acute								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Paronychia								
Female	1	(0.7)	1	1.26	1	(0.7)	2	2.48
Male	0				0			
Periodontitis								
Female	0				0			
Male	2	(1.3)	2	2.26	0			
Pharyngitis								
Female	2	(1.5)	2	2.53	3	(2.1)	3	3.72
Male	1	(0.6)	1	1.13	3	(2.0)	3	3.48
Pharyngotonsillitis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pneumonia								
Female	0				0			
Male	3	(1.9)	3	3.40	1	(0.7)	1	1.16
Pneumonia viral								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Post procedural infection								
Female	0				0			
Male	0				1	(0.7)	1	1.16

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulmonary tuberculoma								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pulpitis dental								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Respiratory syncytial virus infection								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Respiratory tract infection								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Respiratory tract infection viral								
Female	5	(3.6)	5	6.32	4	(2.8)	5	6.21
Male	1	(0.6)	2	2.26	1	(0.7)	1	1.16
Sepsis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Sinusitis								
Female	2	(1.5)	3	3.79	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
Soft tissue infection								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Tooth abscess								
Female	2	(1.5)	2	2.53	1	(0.7)	1	1.24
Male	0				1	(0.7)	2	2.32
Tooth infection								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Upper respiratory tract infection								
Female	1	(0.7)	1	1.26	2	(1.4)	2	2.48
Male	5	(3.2)	5	5.66	4	(2.7)	4	4.64
Urinary tract infection								
Female	3	(2.2)	3	3.79	3	(2.1)	4	4.96
Male	0				2	(1.3)	3	3.48
Viral infection								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Viral rhinitis								
Female	0				0			
Male	0				1	(0.7)	1	1.16

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral tracheitis								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Vulvovaginal mycotic infection								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Injury, poisoning and procedural complications								
All								
Female	8	(5.8)	11	13.91	9	(6.4)	11	13.65
Male	11	(7.1)	14	15.85	18	(12.0)	24	27.83
Accidental overdose								
Female	0				1	(0.7)	2	2.48
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Accidental underdose								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Animal bite								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Arthropod bite								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Arthropod sting								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Chillblains								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Concussion								
Female	0				1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Contusion								
Female	0				0			
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Crush injury								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Exposure to SARS-CoV-2								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Extra dose administered								
Female	1	(0.7)	1	1.26	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
Fall								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Foot fracture								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Incorrect dose administered								
Female	1	(0.7)	1	1.26	0			
Male	2	(1.3)	2	2.26	1	(0.7)	2	2.32
Joint injury								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Ligament sprain								
Female	0				0			
Male	0				2	(1.3)	2	2.32
Limb injury								
Female	0				2	(1.4)	2	2.48
Male	0				0			
Medication error								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Meniscus injury								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Muscle injury								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Muscle strain								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Overdose								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Product administration error								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Skin abrasion								
Female	1	(0.7)	1	1.26	0			
Male	0				2	(1.3)	2	2.32
Skin laceration								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Spinal column injury								

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.7)	1	1.16
Spinal compression fracture								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Subcutaneous haematoma								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Subdural haematoma								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Thermal burn								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Tooth fracture								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Vaccination complication								
Female	0				2	(1.4)	2	2.48
Male	0				2	(1.3)	2	2.32
Wound								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Wrong product administered								
Female	0				0			
Male	1	(0.6)	2	2.26	1	(0.7)	1	1.16
Investigations								
All								
Female	7	(5.1)	10	12.65	5	(3.5)	5	6.21
Male	5	(3.2)	5	5.66	8	(5.3)	9	10.44
Amylase increased								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Blood alkaline phosphatase increased								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Blood creatinine increased								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Blood pressure increased								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Blood triglycerides increased								

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Blood urine present								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Catheterisation cardiac								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Electrocardiogram abnormal								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Electrocardiogram T wave inversion								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Eosinophil count increased								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Glomerular filtration rate decreased								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Haematocrit increased								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Haemoglobin increased								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Liver function test abnormal								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Liver function test increased								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Platelet count decreased								
Female	0				1	(0.7)	1	1.24
Male	0				0			
SARS-CoV-2 test positive								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Transaminases increased								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Weight increased								
Female	4	(2.9)	4	5.06	0			
Male	2	(1.3)	2	2.26	4	(2.7)	4	4.64

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Female	7	(5.1)	9	11.38	12	(8.5)	13	16.14
Male	8	(5.2)	9	10.19	8	(5.3)	9	10.44
Decreased appetite								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Dehydration								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Dyslipidaemia								
Female	1	(0.7)	1	1.26	2	(1.4)	2	2.48
Male	2	(1.3)	3	3.40	1	(0.7)	1	1.16
Fluid retention								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Hypercholesterolaemia								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Hyperglycaemia								
Female	0				5	(3.5)	5	6.21
Male	0				0			
Hyperkalaemia								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	3	(2.0)	3	3.48
Hypertriglyceridaemia								
Female	1	(0.7)	1	1.26	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
Hypoalbuminaemia								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Hypoglycaemia								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Hypokalaemia								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Hyponatraemia								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Increased appetite								
Female	0				0			
Male	0				1	(0.7)	1	1.16

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipomatosis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Vitamin D deficiency								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Musculoskeletal and connective tissue disorders								
All								
Female	17	(12.4)	21	26.56	19	(13.5)	29	36.00
Male	15	(9.7)	20	22.65	16	(10.7)	19	22.03
Arthralgia								
Female	2	(1.5)	2	2.53	4	(2.8)	4	4.96
Male	3	(1.9)	4	4.53	2	(1.3)	2	2.32
Arthritis								
Female	0				0			
Male	0				2	(1.3)	2	2.32
Back disorder								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Back pain								
Female	4	(2.9)	4	5.06	4	(2.8)	4	4.96
Male	4	(2.6)	4	4.53	7	(4.7)	7	8.12
Bone cyst								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Bone pain								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Coccydynia								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Flank pain								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Foot deformity								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Intervertebral disc protrusion								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Jaw disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle spasms								
Female	0				1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Myalgia								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Myositis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Neck pain								
Female	2	(1.5)	2	2.53	1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	0			
Osteoarthritis								
Female	5	(3.6)	5	6.32	7	(5.0)	8	9.93
Male	0				0			
Osteochondrosis								
Female	0				2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			
Pain in extremity								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				1	(0.7)	2	2.32
Periarthritis								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				0			
Periostitis								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Rotator cuff syndrome								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Spinal osteoarthritis								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	0			
Tendon disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Tendonitis								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Tenosynovitis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Torticollis								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.7)	1	1.16
Trigger finger								
Female	2	(1.5)	2	2.53	0			
Male	2	(1.3)	2	2.26	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	2	(1.5)	2	2.53	3	(2.1)	5	6.21
Male	2	(1.3)	2	2.26	0			
Adrenal adenoma								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Eye naevus								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Lung adenocarcinoma								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Osteoma								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pancreatic neoplasm								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Small cell lung cancer								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Small intestine neuroendocrine tumour								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Uterine cancer								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Uterine leiomyoma								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Nervous system disorders								
All								
Female	10	(7.3)	13	16.44	19	(13.5)	34	42.20
Male	9	(5.8)	19	21.52	10	(6.7)	13	15.08
Anosmia								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.7)	1	1.16
Basilar migraine								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Carpal tunnel syndrome								
Female	2	(1.5)	2	2.53	4	(2.8)	4	4.96
Male	0				0			
Cerebral arteriosclerosis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Cerebrovascular accident								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Cerebrovascular disorder								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Cognitive disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Diabetic neuropathy								
Female	0				2	(1.4)	2	2.48
Male	2	(1.3)	2	2.26	0			
Dizziness								
Female	2	(1.5)	3	3.79	2	(1.4)	3	3.72
Male	3	(1.9)	6	6.79	0			
Dizziness postural								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Dysgeusia								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Essential tremor								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Facial nerve disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Headache								
Female	6	(4.4)	7	8.85	6	(4.3)	7	8.69
Male	2	(1.3)	3	3.40	3	(2.0)	5	5.80
Hemiparesis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Hypoaesthesia								

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				1	(0.7)	1	1.24
Male	0				0			
Hypoglycaemic coma								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Hyporeflexia								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Memory impairment								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				0			
Migraine								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Morton's neuralgia								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Neuropathy peripheral								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Paraesthesia								
Female	0				2	(1.4)	2	2.48
Male	0				1	(0.7)	1	1.16
Sciatica								
Female	0				0			
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Sleep deficit								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Transient ischaemic attack								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Tremor								
Female	0				2	(1.4)	6	7.45
Male	1	(0.6)	1	1.13	0			
Vascular encephalopathy								
Female	0				0			
Male	1	(0.6)	1	1.13	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Female	1	(0.7)	1	1.26	4	(2.8)	4	4.96
Male	1	(0.6)	1	1.13	5	(3.3)	5	5.80
Affect lability								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Depression								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Fear								
Female	0				1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Insomnia								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Mental status changes								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Mixed anxiety and depressive disorder								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Phobia								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Sleep disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Female	0				3	(2.1)	3	3.72
Male	4	(2.6)	7	7.93	3	(2.0)	3	3.48
Acute kidney injury								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Chronic kidney disease								
Female	0				0			
Male	2	(1.3)	2	2.26	1	(0.7)	1	1.16
Dysuria								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Haematuria								
Female	0				0			
Male	1	(0.6)	2	2.26	0			
Hydrocalyx								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Nephropathy								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Renal colic								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Renal cyst								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	0			
Reproductive system and breast disorders								
All								
Female	0				1	(0.7)	1	1.24
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Benign prostatic hyperplasia								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Menopausal disorder								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Respiratory, thoracic and mediastinal disorders								

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Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	8	(5.8)	9	11.38	11	(7.8)	13	16.14
Male	9	(5.8)	11	12.46	8	(5.3)	10	11.60
Asthma								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Bronchitis chronic								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Cough								
Female	2	(1.5)	2	2.53	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	2	(1.3)	2	2.32
Dyspnoea								
Female	0				4	(2.8)	5	6.21
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Emphysema								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Epistaxis								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	2	2.32
Nasal congestion								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Nasal septum deviation								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Oropharyngeal pain								
Female	0				0			
Male	1	(0.6)	1	1.13	2	(1.3)	2	2.32
Paranasal cyst								
Female	0				2	(1.4)	2	2.48
Male	0				0			
Pleurisy								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Pulmonary fibrosis								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Pulmonary hypertension								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Respiratory disorder								
Female	2	(1.5)	2	2.53	2	(1.4)	2	2.48
Male	1	(0.6)	1	1.13	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis allergic								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Rhinorrhoea								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Sinus congestion								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Sinus pain								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Skin and subcutaneous tissue disorders								
All								
Female	6	(4.4)	6	7.59	9	(6.4)	9	11.17
Male	6	(3.9)	7	7.93	6	(4.0)	7	8.12
Alopecia								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Blister								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Cold sweat								
Female	0				1	(0.7)	1	1.24
Male	2	(1.3)	2	2.26	0			
Dermatitis contact								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Eczema								
Female	1	(0.7)	1	1.26	1	(0.7)	1	1.24
Male	0				1	(0.7)	1	1.16
Hyperhidrosis								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Hyperkeratosis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Intertrigo								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Lipohypertrophy								
Female	0				0			
Male	0				1	(0.7)	1	1.16

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pruritus								
Female	0				3	(2.1)	3	3.72
Male	1	(0.6)	1	1.13	0			
Rash								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Seborrhoea								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Skin reaction								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Skin ulcer								
Female	0				0			
Male	2	(1.3)	2	2.26	2	(1.3)	2	2.32
Umbilical haematoma								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Urticaria								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Surgical and medical procedures								
All								
Female	1	(0.7)	1	1.26	0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Cardiac pacemaker replacement								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Shoulder operation								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Tooth extraction								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Vascular disorders								
All								
Female	4	(2.9)	4	5.06	9	(6.4)	12	14.89
Male	4	(2.6)	8	9.06	7	(4.7)	7	8.12
Aortic arteriosclerosis								
Female	0				2	(1.4)	2	2.48
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by sex, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Blood pressure fluctuation								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Deep vein thrombosis								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Diabetic vascular disorder								
Female	0				0			
Male	1	(0.6)	1	1.13	1	(0.7)	1	1.16
Haematoma								
Female	1	(0.7)	1	1.26	0			
Male	0				1	(0.7)	1	1.16
Hypertension								
Female	0				3	(2.1)	3	3.72
Male	2	(1.3)	2	2.26	3	(2.0)	3	3.48
Hypertensive crisis								
Female	1	(0.7)	1	1.26	1	(0.7)	3	3.72
Male	0				0			
Hypertensive urgency								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Hypotension								
Female	0				1	(0.7)	1	1.24
Male	0				0			
Neovascularisation								
Female	0				0			
Male	0				1	(0.7)	1	1.16
Orthostatic hypotension								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Peripheral arterial occlusive disease								
Female	0				0			
Male	1	(0.6)	1	1.13	0			
Peripheral artery stenosis								
Female	0				0			
Male	1	(0.6)	3	3.40	0			
Peripheral venous disease								
Female	1	(0.7)	1	1.26	0			
Male	0				0			
Thrombophlebitis								
Female	0				1	(0.7)	1	1.24
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.8 Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	125				120			
Male	165				172			
PYE (years)								
Female	61.37				59.03			
Male	80.94				85.09			
Events								
Female	85	(68.0)	219	356.87	82	(68.3)	242	409.94
Male	104	(63.0)	288	355.81	108	(62.8)	377	443.08
Blood and lymphatic system disorders								
All								
Female	0				2	(1.7)	2	3.39
Male	3	(1.8)	3	3.71	1	(0.6)	1	1.18
Anaemia								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Iron deficiency anaemia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Lymphadenitis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Lymphadenopathy								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Thrombocytopenia								
Female	0				0			
Male	0				1	(0.6)	1	1.18

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Female	4	(3.2)	4	6.52	2	(1.7)	3	5.08
Male	5	(3.0)	5	6.18	3	(1.7)	3	3.53
Angina pectoris								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Angina unstable								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Atrial fibrillation								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Bundle branch block right								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Cardiac failure								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Cardiomegaly								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Cardiovascular disorder								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Myocardial ischaemia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Palpitations								
Female	1	(0.8)	1	1.63	0			
Male	0				2	(1.2)	2	2.35
Ventricular extrasystoles								
Female	2	(1.6)	2	3.26	0			
Male	1	(0.6)	1	1.24	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Female	2	(1.6)	2	3.26	2	(1.7)	2	3.39
Male	0				0			
Deafness neurosensory								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Ear pain								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Vertigo								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Endocrine disorders								
All								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Hypothyroidism								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Eye disorders								
All								
Female	11	(8.8)	13	21.18	10	(8.3)	10	16.94
Male	18	(10.9)	24	29.65	18	(10.5)	27	31.73
Arteriosclerotic retinopathy								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Astigmatism								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Cataract								
Female	2	(1.6)	2	3.26	0			
Male	2	(1.2)	2	2.47	2	(1.2)	2	2.35
Cataract nuclear								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Conjunctival haemorrhage								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Corneal erosion								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Diabetic retinal oedema								
Female	0				1	(0.8)	1	1.69
Male	2	(1.2)	2	2.47	0			
Diabetic retinopathy								
Female	3	(2.4)	3	4.89	3	(2.5)	3	5.08
Male	9	(5.5)	9	11.12	11	(6.4)	11	12.93
Dry eye								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Epiretinal membrane								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Glaucoma								
Female	0				3	(2.5)	3	5.08
Male	1	(0.6)	1	1.24	0			
Macular oedema								
Female	3	(2.4)	4	6.52	0			
Male	0				1	(0.6)	1	1.18
Myopia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Non-proliferative retinopathy								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	2	(1.2)	2	2.35
Ocular hypertension								
Female	0				0			
Male	0				1	(0.6)	2	2.35
Photopsia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Posterior capsule opacification								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Presbyopia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Pterygium								
Female	0				1	(0.8)	1	1.69
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal vascular disorder								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Retinopathy								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Retinopathy hypertensive								
Female	0				0			
Male	2	(1.2)	2	2.47	0			
Vision blurred								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	0			
Vitreous detachment								
Female	0				1	(0.8)	1	1.69
Male	0				1	(0.6)	1	1.18
Vitreous floaters								
Female	0				0			
Male	0				2	(1.2)	2	2.35
Gastrointestinal disorders								
All								
Female	13	(10.4)	14	22.81	15	(12.5)	23	38.96
Male	13	(7.9)	24	29.65	9	(5.2)	18	21.15
Abdominal discomfort								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Abdominal distension								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Abdominal pain								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Abdominal pain upper								
Female	1	(0.8)	1	1.63	0			
Male	2	(1.2)	2	2.47	1	(0.6)	1	1.18
Anal fissure								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Chronic gastritis								
Female	0				0			
Male	1	(0.6)	1	1.24	2	(1.2)	2	2.35
Constipation								
Female	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.6)	1	1.24	0			
Dental caries								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Diarrhoea								
Female	2	(1.6)	2	3.26	2	(1.7)	3	5.08
Male	3	(1.8)	4	4.94	2	(1.2)	2	2.35
Diverticulum intestinal								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Dyspepsia								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Faeces soft								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Gastric polyps								
Female	0				1	(0.8)	1	1.69
Male	0				1	(0.6)	1	1.18
Gastritis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Gastritis erosive								
Female	0				2	(1.7)	2	3.39
Male	0				0			
Gastrooesophageal reflux disease								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Gingival recession								
Female	0				0			
Male	0				1	(0.6)	2	2.35
Haemorrhoids								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Hiatus hernia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Impaired gastric emptying								
Female	0				0			
Male	1	(0.6)	2	2.47	0			
Irritable bowel syndrome								
Female	0				0			
Male	1	(0.6)	1	1.24	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lumbar hernia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Nausea								
Female	2	(1.6)	2	3.26	6	(5.0)	6	10.16
Male	2	(1.2)	2	2.47	2	(1.2)	2	2.35
Odynophagia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Pancreatic failure								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Pneumatosis intestinalis								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Toothache								
Female	2	(1.6)	2	3.26	2	(1.7)	3	5.08
Male	0				1	(0.6)	2	2.35
Vomiting								
Female	3	(2.4)	3	4.89	3	(2.5)	3	5.08
Male	4	(2.4)	4	4.94	2	(1.2)	2	2.35
General disorders and administration site conditions								
All								
Female	16	(12.8)	20	32.59	18	(15.0)	26	44.04
Male	25	(15.2)	30	37.06	16	(9.3)	57	66.99
Asthenia								
Female	0				1	(0.8)	1	1.69
Male	0				1	(0.6)	1	1.18
Chest pain								
Female	0				0			
Male	0				2	(1.2)	2	2.35
Fatigue								
Female	4	(3.2)	5	8.15	0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Hunger								
Female	1	(0.8)	1	1.63	1	(0.8)	2	3.39
Male	0				0			
Hyperthermia								
Female	0				1	(0.8)	1	1.69
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inflammation								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Influenza like illness								
Female	0				1	(0.8)	1	1.69
Male	3	(1.8)	3	3.71	0			
Injection site mass								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Injection site pain								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Injection site urticaria								
Female	1	(0.8)	2	3.26	0			
Male	0				0			
Malaise								
Female	1	(0.8)	1	1.63	1	(0.8)	2	3.39
Male	2	(1.2)	2	2.47	2	(1.2)	42	49.36
Medical device site bruise								
Female	0				0			
Male	2	(1.2)	2	2.47	0			
Medical device site dermatitis								
Female	1	(0.8)	1	1.63	2	(1.7)	3	5.08
Male	2	(1.2)	2	2.47	1	(0.6)	1	1.18
Medical device site erythema								
Female	0				2	(1.7)	3	5.08
Male	0				1	(0.6)	1	1.18
Medical device site haematoma								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Medical device site haemorrhage								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Medical device site irritation								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Medical device site pain								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Medical device site pruritus								
Female	0				0			
Male	1	(0.6)	1	1.24	3	(1.7)	3	3.53
Medical device site rash								

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	2	(1.6)	2	3.26	5	(4.2)	5	8.47
Male	4	(2.4)	4	4.94	2	(1.2)	2	2.35
Medical device site reaction								
Female	1	(0.8)	1	1.63	0			
Male	2	(1.2)	2	2.47	0			
Oedema peripheral								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Pain								
Female	1	(0.8)	1	1.63	0			
Male	2	(1.2)	2	2.47	0			
Pyrexia								
Female	5	(4.0)	5	8.15	4	(3.3)	4	6.78
Male	4	(2.4)	5	6.18	2	(1.2)	2	2.35
Swelling face								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Vaccination site pain								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Hepatobiliary disorders								
All								
Female	3	(2.4)	4	6.52	1	(0.8)	1	1.69
Male	2	(1.2)	2	2.47	3	(1.7)	3	3.53
Gallbladder disorder								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Gallbladder polyp								
Female	1	(0.8)	1	1.63	0			
Male	0				2	(1.2)	2	2.35
Hepatic calcification								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hepatic steatosis								
Female	2	(1.6)	2	3.26	0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Hypertransaminasaemia								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Female	2	(1.6)	2	3.26	0			
Male	0				1	(0.6)	1	1.18
Hypersensitivity								
Female	2	(1.6)	2	3.26	0			
Male	0				0			
Seasonal allergy								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Infections and infestations								
All								
Female	51	(40.8)	75	122.22	45	(37.5)	71	120.27
Male	53	(32.1)	72	88.95	56	(32.6)	77	90.50
Abscess limb								
Female	1	(0.8)	1	1.63	0			
Male	0				1	(0.6)	2	2.35
Acute sinusitis								
Female	0				1	(0.8)	1	1.69
Male	0				2	(1.2)	2	2.35
Breast abscess								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Bronchitis								
Female	2	(1.6)	2	3.26	2	(1.7)	2	3.39
Male	2	(1.2)	2	2.47	0			
Conjunctivitis								
Female	2	(1.6)	2	3.26	0			
Male	2	(1.2)	2	2.47	0			
Coronavirus infection								
Female	0				1	(0.8)	1	1.69
Male	0				0			
COVID-19								
Female	12	(9.6)	13	21.18	12	(10.0)	12	20.33
Male	17	(10.3)	17	21.00	20	(11.6)	22	25.86
COVID-19 pneumonia								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
Female	3	(2.4)	3	4.89	1	(0.8)	1	1.69
Male	0				0			
Cystitis escherichia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Eye infection								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Fungal skin infection								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Gastric infection								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Gastroenteritis								
Female	4	(3.2)	4	6.52	2	(1.7)	2	3.39
Male	2	(1.2)	3	3.71	0			
Gastroenteritis viral								
Female	1	(0.8)	1	1.63	2	(1.7)	2	3.39
Male	0				0			
Gastrointestinal infection								
Female	0				0			
Male	1	(0.6)	1	1.24	2	(1.2)	3	3.53
Genital infection fungal								
Female	1	(0.8)	2	3.26	0			
Male	0				0			
Gingivitis								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Herpes zoster								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Hordeolum								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Infected cyst								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Influenza								
Female	0				3	(2.5)	3	5.08
Male	1	(0.6)	1	1.24	2	(1.2)	2	2.35

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Localised infection								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Lower respiratory tract infection								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Nasopharyngitis								
Female	18	(14.4)	21	34.22	17	(14.2)	19	32.19
Male	16	(9.7)	21	25.94	19	(11.0)	24	28.21
Norovirus infection								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Otitis externa								
Female	0				1	(0.8)	1	1.69
Male	0				2	(1.2)	2	2.35
Otitis media								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Periodontitis								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Pharyngitis								
Female	4	(3.2)	4	6.52	1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Pneumonia								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Respiratory tract infection								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Respiratory tract infection viral								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	2	(1.2)	2	2.47	1	(0.6)	1	1.18
Rhinitis								
Female	0				1	(0.8)	2	3.39
Male	2	(1.2)	2	2.47	3	(1.7)	3	3.53
Severe acute respiratory syndrome								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinusitis								
Female	2	(1.6)	2	3.26	2	(1.7)	2	3.39
Male	3	(1.8)	3	3.71	0			
Skin infection								
Female	0				0			
Male	0				2	(1.2)	2	2.35
Tinea cruris								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Tinea pedis								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Tonsillitis								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Tooth abscess								
Female	0				0			
Male	2	(1.2)	2	2.47	0			
Tooth infection								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Upper respiratory tract infection								
Female	3	(2.4)	3	4.89	3	(2.5)	4	6.78
Male	3	(1.8)	3	3.71	4	(2.3)	4	4.70
Urinary tract infection								
Female	6	(4.8)	6	9.78	6	(5.0)	8	13.55
Male	0				0			
Vaginal infection								
Female	1	(0.8)	2	3.26	0			
Male	0				0			
Viral infection								
Female	0				0			
Male	1	(0.6)	1	1.24	4	(2.3)	4	4.70
Vulvitis								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Vulvovaginitis								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Injury, poisoning and procedural complications								

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	10	(8.0)	14	22.81	10	(8.3)	12	20.33
Male	20	(12.1)	23	28.42	23	(13.4)	27	31.73
Accidental overdose								
Female	2	(1.6)	3	4.89	0			
Male	5	(3.0)	5	6.18	1	(0.6)	1	1.18
Anaemia postoperative								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Animal scratch								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Arthropod bite								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Back injury								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Burns first degree								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Clavicle fracture								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Contusion								
Female	0				0			
Male	1	(0.6)	1	1.24	2	(1.2)	2	2.35
Corneal abrasion								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Epicondylitis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Face injury								
Female	1	(0.8)	1	1.63	0			
Male	0				1	(0.6)	1	1.18
Fall								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Fibula fracture								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Hand fracture								

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Heat stroke								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Incorrect dose administered								
Female	1	(0.8)	1	1.63	0			
Male	2	(1.2)	2	2.47	0			
Joint injury								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Ligament sprain								
Female	2	(1.6)	2	3.26	0			
Male	1	(0.6)	1	1.24	0			
Limb injury								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Medication error								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Muscle strain								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Nerve injury								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Prescribed overdose								
Female	2	(1.6)	2	3.26	0			
Male	3	(1.8)	3	3.71	0			
Procedural pain								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Product administration error								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Product dispensing error								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Radius fracture								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Road traffic accident								
Female	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.6)	2	2.47	0			
Skin abrasion								
Female	1	(0.8)	2	3.26	1	(0.8)	1	1.69
Male	0				0			
Skin laceration								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Tooth fracture								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Vaccination complication								
Female	0				3	(2.5)	4	6.78
Male	5	(3.0)	5	6.18	5	(2.9)	7	8.23
Wound								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Wound dehiscence								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Wrong product administered								
Female	0				1	(0.8)	1	1.69
Male	0				3	(1.7)	3	3.53
Investigations								
All								
Female	4	(3.2)	4	6.52	6	(5.0)	8	13.55
Male	10	(6.1)	11	13.59	7	(4.1)	7	8.23
Angiogram								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Aspartate aminotransferase increased								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Blood cholesterol increased								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Blood glucose increased								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Blood pressure increased								
Female	0				0			
Male	2	(1.2)	2	2.47	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood testosterone decreased								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Blood triglycerides increased								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Blood uric acid increased								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Cardiac murmur								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Electrocardiogram abnormal								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Eosinophil count increased								
Female	0				1	(0.8)	2	3.39
Male	0				0			
Haemoglobin decreased								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Heart rate increased								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hepatic enzyme increased								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Hepatitis B virus test positive								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Lipids abnormal								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Low density lipoprotein increased								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Mycobacterium tuberculosis complex test positive								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Occult blood positive								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
SARS-CoV-2 test positive								

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				2	(1.7)	2	3.39
Male	0				2	(1.2)	2	2.35
Weight decreased								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Weight increased								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
White blood cell count decreased								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Metabolism and nutrition disorders								
All								
Female	3	(2.4)	3	4.89	3	(2.5)	3	5.08
Male	5	(3.0)	7	8.65	6	(3.5)	8	9.40
Dehydration								
Female	0				0			
Male	0				1	(0.6)	2	2.35
Hypercholesterolaemia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Hyperuricaemia								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hypoglycaemia								
Female	2	(1.6)	2	3.26	1	(0.8)	1	1.69
Male	3	(1.8)	5	6.18	2	(1.2)	3	3.53
Hyponatraemia								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Insulin resistance								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Obesity								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Vitamin D deficiency								
Female	1	(0.8)	1	1.63	2	(1.7)	2	3.39
Male	0				0			
Musculoskeletal and connective tissue disorders								

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	13	(10.4)	15	24.44	16	(13.3)	20	33.88
Male	14	(8.5)	16	19.77	23	(13.4)	43	50.54
Arthralgia								
Female	3	(2.4)	3	4.89	2	(1.7)	2	3.39
Male	3	(1.8)	3	3.71	7	(4.1)	7	8.23
Arthritis								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Back pain								
Female	0				4	(3.3)	4	6.78
Male	3	(1.8)	3	3.71	7	(4.1)	21	24.68
Bursitis								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Chondromalacia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Groin pain								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Limb discomfort								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Limb mass								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Muscle spasms								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	0			
Muscular weakness								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Musculoskeletal stiffness								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Myalgia								
Female	1	(0.8)	1	1.63	4	(3.3)	4	6.78
Male	1	(0.6)	1	1.24	3	(1.7)	4	4.70
Neck pain								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nodal osteoarthritis								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Osteoarthritis								
Female	1	(0.8)	1	1.63	2	(1.7)	2	3.39
Male	2	(1.2)	2	2.47	0			
Pain in extremity								
Female	2	(1.6)	2	3.26	2	(1.7)	2	3.39
Male	4	(2.4)	4	4.94	4	(2.3)	4	4.70
Periarthritis								
Female	0				2	(1.7)	2	3.39
Male	0				1	(0.6)	1	1.18
Rheumatoid arthritis								
Female	0				2	(1.7)	2	3.39
Male	0				0			
Synovial cyst								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Tendonitis								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Tenosynovitis								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Trigger finger								
Female	2	(1.6)	2	3.26	0			
Male	0				1	(0.6)	1	1.18

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	3	(2.4)	3	4.89	2	(1.7)	3	5.08
Male	1	(0.6)	1	1.24	0			
Benign neoplasm of thyroid gland								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Benign renal neoplasm								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Eye naevus								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Haemangioma of liver								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Melanocytic naevus								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Uterine leiomyoma								
Female	0				2	(1.7)	2	3.39
Male	0				0			
Nervous system disorders								
All								
Female	9	(7.2)	12	19.55	17	(14.2)	22	37.27
Male	18	(10.9)	34	42.01	7	(4.1)	56	65.82
Autonomic nervous system imbalance								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Burning sensation								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Carpal tunnel syndrome								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Cervicobrachial syndrome								
Female	0				0			
Male	1	(0.6)	1	1.24	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic neuropathy								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Disturbance in attention								
Female	0				0			
Male	1	(0.6)	9	11.12	0			
Dizziness								
Female	0				0			
Male	2	(1.2)	3	3.71	2	(1.2)	3	3.53
Dizziness postural								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Encephalopathy								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Haemorrhage intracranial								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Headache								
Female	5	(4.0)	8	13.04	9	(7.5)	12	20.33
Male	8	(4.8)	11	13.59	1	(0.6)	1	1.18
Hypoaesthesia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Hypoglycaemic seizure								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Hypoglycaemic unconsciousness								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Hypotonia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Loss of consciousness								
Female	1	(0.8)	1	1.63	0			
Male	0				1	(0.6)	1	1.18
Migraine								
Female	1	(0.8)	1	1.63	2	(1.7)	2	3.39
Male	1	(0.6)	2	2.47	0			
Neuropathy peripheral								
Female	0				1	(0.8)	1	1.69
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post herpetic neuralgia								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Sinus headache								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Somnolence								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Speech disorder								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Syncope								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Tremor								
Female	0				0			
Male	1	(0.6)	1	1.24	2	(1.2)	49	57.59
Psychiatric disorders								
All								
Female	2	(1.6)	2	3.26	3	(2.5)	4	6.78
Male	3	(1.8)	3	3.71	3	(1.7)	3	3.53
Anxiety								
Female	1	(0.8)	1	1.63	2	(1.7)	2	3.39
Male	0				2	(1.2)	2	2.35
Attention deficit hyperactivity disorder								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Depressed mood								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Depression								
Female	0				2	(1.7)	2	3.39
Male	0				1	(0.6)	1	1.18
Insomnia								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Sleep disorder								
Female	0				0			
Male	1	(0.6)	1	1.24	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Female	1	(0.8)	1	1.63	1	(0.8)	4	6.78
Male	2	(1.2)	2	2.47	2	(1.2)	2	2.35
Chronic kidney disease								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Diabetic nephropathy								
Female	0				1	(0.8)	1	1.69
Male	0				1	(0.6)	1	1.18
Hydrocalyx								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Hypertensive nephropathy								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Microalbuminuria								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Renal cyst								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Renal pain								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Female	2	(1.6)	2	3.26	3	(2.5)	5	8.47
Male	2	(1.2)	2	2.47	1	(0.6)	1	1.18
Benign prostatic hyperplasia								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Dysmenorrhoea								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Ectropion of cervix								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Fibrocystic breast disease								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Ovarian disorder								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Penile pain								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Premenstrual syndrome								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	0				0			
Prostatomegaly								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Respiratory, thoracic and mediastinal disorders								
All								
Female	10	(8.0)	13	21.18	8	(6.7)	12	20.33
Male	11	(6.7)	13	16.06	13	(7.6)	17	19.98
Allergic cough								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Bronchial hyperreactivity								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cough								
Female	3	(2.4)	5	8.15	4	(3.3)	5	8.47
Male	0				4	(2.3)	4	4.70
Dyspnoea exertional								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Epistaxis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hiccups								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Nasal congestion								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Oropharyngeal pain								
Female	3	(2.4)	3	4.89	2	(1.7)	2	3.39
Male	2	(1.2)	2	2.47	1	(0.6)	1	1.18
Pleurisy								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Productive cough								
Female	0				0			
Male	0				2	(1.2)	2	2.35
Pulmonary congestion								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Respiratory disorder								
Female	1	(0.8)	1	1.63	1	(0.8)	1	1.69
Male	3	(1.8)	3	3.71	1	(0.6)	1	1.18
Rhinitis allergic								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Rhinorrhoea								
Female	0				2	(1.7)	2	3.39
Male	2	(1.2)	2	2.47	4	(2.3)	4	4.70
Sinus congestion								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Sneezing								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

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Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Throat irritation								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Upper-airway cough syndrome								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Skin and subcutaneous tissue disorders								
All								
Female	13	(10.4)	13	21.18	9	(7.5)	9	15.25
Male	11	(6.7)	11	13.59	15	(8.7)	23	27.03
Alopecia								
Female	2	(1.6)	2	3.26	0			
Male	1	(0.6)	1	1.24	0			
Angioedema								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Blister								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Chronic spontaneous urticaria								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Cold sweat								
Female	0				2	(1.7)	2	3.39
Male	0				3	(1.7)	7	8.23
Dermal cyst								
Female	0				1	(0.8)	1	1.69
Male	1	(0.6)	1	1.24	0			
Dermatitis								
Female	3	(2.4)	3	4.89	0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Dermatitis atopic								
Female	0				1	(0.8)	1	1.69
Male	0				1	(0.6)	1	1.18
Dermatitis contact								
Female	1	(0.8)	1	1.63	4	(3.3)	4	6.78
Male	1	(0.6)	1	1.24	2	(1.2)	2	2.35
Dry skin								
Female	0				0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Eczema								
Female	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.6)	1	1.18
Erythema								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Hidradenitis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hyperkeratosis								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Ingrown hair								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Lichen sclerosus								
Female	1	(0.8)	1	1.63	0			
Male	0				0			
Macule								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Pruritus								
Female	0				0			
Male	0				1	(0.6)	1	1.18
Rash								
Female	2	(1.6)	2	3.26	0			
Male	1	(0.6)	1	1.24	0			
Rash erythematous								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Skin irritation								
Female	1	(0.8)	1	1.63	0			
Male	1	(0.6)	1	1.24	1	(0.6)	1	1.18
Skin lesion								
Female	1	(0.8)	1	1.63	0			
Male	0				1	(0.6)	1	1.18
Telangiectasia								
Female	0				1	(0.8)	1	1.69
Male	0				0			
Urticaria								
Female	0				0			
Male	0				3	(1.7)	3	3.53
Xeroderma								
Female	1	(0.8)	1	1.63	0			
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by sex, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Female	0				0			
Male	2	(1.2)	2	2.47	0			
Cardiac ablation								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Skin neoplasm excision								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Vascular disorders								
All								
Female	3	(2.4)	3	4.89	1	(0.8)	1	1.69
Male	3	(1.8)	3	3.71	3	(1.7)	3	3.53
Arteriosclerosis								
Female	0				0			
Male	1	(0.6)	1	1.24	0			
Hypertension								
Female	3	(2.4)	3	4.89	0			
Male	2	(1.2)	2	2.47	3	(1.7)	3	3.53
Varicose vein								
Female	0				1	(0.8)	1	1.69
Male	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.9 Adverse events by age group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	333				332			
>=65 - <75 years	134				144			
>=75 years	25				16			
PYE (years)								
>=18 - <65 years	329.13				329.36			
>=65 - <75 years	132.08				140.33			
>=75 years	24.67				15.35			
Events								
>=18 - <65 years	235	(70.6)	771	234.25	220	(66.3)	759	230.45
>=65 - <75 years	95	(70.9)	357	270.29	104	(72.2)	373	265.80
>=75 years	21	(84.0)	99	401.33	11	(68.8)	30	195.46
Serious								
Yes								
>=18 - <65 years	22	(6.6)	29	8.81	28	(8.4)	36	10.93
>=65 - <75 years	23	(17.2)	37	28.01	19	(13.2)	35	24.94
>=75 years	6	(24.0)	8	32.43	2	(12.5)	2	13.03
No								
>=18 - <65 years	231	(69.4)	742	225.44	217	(65.4)	723	219.52
>=65 - <75 years	87	(64.9)	320	242.28	101	(70.1)	338	240.86
>=75 years	20	(80.0)	91	368.90	10	(62.5)	28	182.43
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
>=18 - <65 years	9	(2.7)	11	3.34	11	(3.3)	13	3.95
>=65 - <75 years	7	(5.2)	12	9.09	7	(4.9)	19	13.54
>=75 years	2	(8.0)	3	12.16	2	(12.5)	2	13.03
Moderate								
>=18 - <65 years	98	(29.4)	177	53.78	94	(28.3)	169	51.31
>=65 - <75 years	47	(35.1)	82	62.08	41	(28.5)	81	57.72
>=75 years	7	(28.0)	21	85.13	1	(6.3)	1	6.52
Mild								
>=18 - <65 years	196	(58.9)	583	177.13	186	(56.0)	577	175.19
>=65 - <75 years	78	(58.2)	263	199.12	90	(62.5)	273	194.54
>=75 years	18	(72.0)	75	304.04	10	(62.5)	27	175.91
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Related to basal insulin								
Probable								
>=18 - <65 years	14	(4.2)	22	6.68	23	(6.9)	33	10.02
>=65 - <75 years	4	(3.0)	4	3.03	6	(4.2)	12	8.55
>=75 years	1	(4.0)	1	4.05	0			
Possible								
>=18 - <65 years	23	(6.9)	32	9.72	18	(5.4)	25	7.59
>=65 - <75 years	10	(7.5)	13	9.84	12	(8.3)	20	14.25
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Unlikely								
>=18 - <65 years	230	(69.1)	716	217.54	212	(63.9)	700	212.53
>=65 - <75 years	92	(68.7)	340	257.42	102	(70.8)	341	243.00
>=75 years	21	(84.0)	97	393.22	11	(68.8)	29	188.94
Missing								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
No								
>=18 - <65 years	234	(70.3)	770	233.95	220	(66.3)	758	230.14
>=65 - <75 years	95	(70.9)	357	270.29	104	(72.2)	373	265.80
>=75 years	21	(84.0)	99	401.33	11	(68.8)	30	195.46
NA								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	2	1.43
>=75 years	1	(4.0)	2	8.11	1	(6.3)	1	6.52
Not recovered/not resolved								
>=18 - <65 years	98	(29.4)	178	54.08	89	(26.8)	169	51.31
>=65 - <75 years	49	(36.6)	118	89.34	65	(45.1)	114	81.24
>=75 years	10	(40.0)	28	113.51	5	(31.3)	7	45.61
Recovered/resolved with sequelae								
>=18 - <65 years	2	(0.6)	2	0.61	3	(0.9)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	2	(1.4)	3	2.14
>=75 years	2	(8.0)	2	8.11	0			
Recovering/resolving								
>=18 - <65 years	12	(3.6)	19	5.77	14	(4.2)	14	4.25
>=65 - <75 years	4	(3.0)	4	3.03	6	(4.2)	7	4.99
>=75 years	3	(12.0)	3	12.16	0			
Recovered/resolved								
>=18 - <65 years	207	(62.2)	570	173.18	198	(59.6)	573	173.97
>=65 - <75 years	82	(61.2)	232	175.65	85	(59.0)	247	176.02
>=75 years	19	(76.0)	64	259.45	10	(62.5)	22	143.34
Unknown								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.10 Adverse events by age group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	144				149			
>=65 - <75 years	99				99			
>=75 years	19				15			
PYE (years)								
>=18 - <65 years	85.31				87.79			
>=65 - <75 years	58.97				56.04			
>=75 years	10.97				8.94			
Events								
>=18 - <65 years	93	(64.6)	292	342.28	83	(55.7)	211	240.34
>=65 - <75 years	54	(54.5)	148	251.00	43	(43.4)	100	178.45
>=75 years	14	(73.7)	26	237.00	8	(53.3)	17	190.12
Serious								
Yes								
>=18 - <65 years	13	(9.0)	15	17.58	6	(4.0)	6	6.83
>=65 - <75 years	7	(7.1)	12	20.35	9	(9.1)	13	23.20
>=75 years	2	(10.5)	3	27.35	1	(6.7)	1	11.18
No								
>=18 - <65 years	92	(63.9)	277	324.69	82	(55.0)	205	233.51
>=65 - <75 years	53	(53.5)	136	230.64	38	(38.4)	87	155.25
>=75 years	13	(68.4)	23	209.65	8	(53.3)	16	178.93
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Severity								
Severe								
>=18 - <65 years	6	(4.2)	9	10.55	7	(4.7)	8	9.11
>=65 - <75 years	4	(4.0)	6	10.18	4	(4.0)	5	8.92
>=75 years	1	(5.3)	2	18.23	0			
Moderate								
>=18 - <65 years	39	(27.1)	74	86.74	32	(21.5)	52	59.23
>=65 - <75 years	22	(22.2)	44	74.62	19	(19.2)	26	46.40
>=75 years	3	(15.8)	4	36.46	3	(20.0)	4	44.73
Mild								
>=18 - <65 years	77	(53.5)	209	244.98	71	(47.7)	151	172.00
>=65 - <75 years	44	(44.4)	98	166.20	32	(32.3)	69	123.13
>=75 years	11	(57.9)	20	182.31	6	(40.0)	13	145.38
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
>=18 - <65 years	4	(2.8)	4	4.69	2	(1.3)	4	4.56
>=65 - <75 years	4	(4.0)	4	6.78	3	(3.0)	4	7.14
>=75 years	1	(5.3)	1	9.12	1	(6.7)	5	55.92
Possible								
>=18 - <65 years	9	(6.3)	15	17.58	5	(3.4)	5	5.70
>=65 - <75 years	7	(7.1)	11	18.66	2	(2.0)	2	3.57
>=75 years	0				0			
Unlikely								
>=18 - <65 years	91	(63.2)	266	311.80	80	(53.7)	200	227.81
>=65 - <75 years	51	(51.5)	130	220.47	43	(43.4)	94	167.74
>=75 years	13	(68.4)	25	227.88	7	(46.7)	11	123.02
Missing								
>=18 - <65 years	3	(2.1)	7	8.21	2	(1.3)	2	2.28
>=65 - <75 years	3	(3.0)	3	5.09	0			
>=75 years	0				1	(6.7)	1	11.18
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
No								
>=18 - <65 years	93	(64.6)	285	334.07	81	(54.4)	207	235.78
>=65 - <75 years	53	(53.5)	143	242.52	43	(43.4)	100	178.45
>=75 years	14	(73.7)	26	237.00	7	(46.7)	16	178.93
NA								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Missing								
>=18 - <65 years	3	(2.1)	7	8.21	2	(1.3)	2	2.28
>=65 - <75 years	3	(3.0)	3	5.09	0			
>=75 years	0				1	(6.7)	1	11.18

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	2	(2.0)	2	3.57
>=75 years	1	(5.3)	2	18.23	0			
Not recovered/not resolved								
>=18 - <65 years	31	(21.5)	52	60.95	28	(18.8)	37	42.15
>=65 - <75 years	20	(20.2)	40	67.84	16	(16.2)	22	39.26
>=75 years	4	(21.1)	5	45.58	4	(26.7)	4	44.73
Recovered/resolved with sequelae								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Recovering/resolving								
>=18 - <65 years	14	(9.7)	19	22.27	9	(6.0)	10	11.39
>=65 - <75 years	5	(5.1)	5	8.48	6	(6.1)	6	10.71
>=75 years	0				1	(6.7)	1	11.18
Recovered/resolved								
>=18 - <65 years	77	(53.5)	221	259.05	67	(45.0)	164	186.81
>=65 - <75 years	45	(45.5)	102	172.98	28	(28.3)	69	123.13
>=75 years	13	(68.4)	19	173.19	5	(33.3)	12	134.20
Unknown								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.11 Adverse events by age group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	189				184			
>=65 - <75 years	92				96			
>=75 years	10				11			
PYE (years)								
>=18 - <65 years	108.79				105.57			
>=65 - <75 years	53.20				54.69			
>=75 years	5.37				6.54			
Events								
>=18 - <65 years	100	(52.9)	239	219.70	98	(53.3)	336	318.28
>=65 - <75 years	63	(68.5)	201	377.81	62	(64.6)	203	371.16
>=75 years	8	(80.0)	15	279.10	7	(63.6)	11	168.32
Serious								
Yes								
>=18 - <65 years	7	(3.7)	7	6.43	17	(9.2)	25	23.68
>=65 - <75 years	14	(15.2)	27	50.75	8	(8.3)	8	14.63
>=75 years	1	(10.0)	1	18.61	0			
No								
>=18 - <65 years	99	(52.4)	232	213.26	95	(51.6)	311	294.59
>=65 - <75 years	58	(63.0)	174	327.06	58	(60.4)	195	356.53
>=75 years	7	(70.0)	14	260.49	7	(63.6)	11	168.32
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Severity								
Severe								
>=18 - <65 years	6	(3.2)	6	5.52	6	(3.3)	7	6.63
>=65 - <75 years	6	(6.5)	13	24.44	6	(6.3)	7	12.80
>=75 years	1	(10.0)	1	18.61	0			
Moderate								
>=18 - <65 years	32	(16.9)	53	48.72	42	(22.8)	89	84.31
>=65 - <75 years	26	(28.3)	45	84.58	17	(17.7)	28	51.19
>=75 years	1	(10.0)	1	18.61	2	(18.2)	4	61.21
Mild								
>=18 - <65 years	81	(42.9)	180	165.46	89	(48.4)	240	227.34
>=65 - <75 years	51	(55.4)	143	268.79	54	(56.3)	168	307.16
>=75 years	6	(60.0)	13	241.89	5	(45.5)	7	107.11
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
>=18 - <65 years	5	(2.6)	8	7.35	5	(2.7)	6	5.68
>=65 - <75 years	4	(4.3)	5	9.40	1	(1.0)	1	1.83
>=75 years	0				1	(9.1)	1	15.30
Possible								
>=18 - <65 years	10	(5.3)	10	9.19	9	(4.9)	19	18.00
>=65 - <75 years	13	(14.1)	24	45.11	7	(7.3)	23	42.05
>=75 years	0				1	(9.1)	1	15.30
Unlikely								
>=18 - <65 years	91	(48.1)	221	203.15	94	(51.1)	311	294.59
>=65 - <75 years	58	(63.0)	172	323.30	61	(63.5)	179	327.28
>=75 years	8	(80.0)	15	279.10	7	(63.6)	9	137.71
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	3	(1.6)	3	2.76	3	(1.6)	4	3.79
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
No								
>=18 - <65 years	99	(52.4)	236	216.94	98	(53.3)	331	313.54
>=65 - <75 years	63	(68.5)	199	374.05	62	(64.6)	203	371.16
>=75 years	8	(80.0)	15	279.10	7	(63.6)	11	168.32
NA								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	3	5.64	0			
>=75 years	0				0			
Not recovered/not resolved								
>=18 - <65 years	47	(24.9)	72	66.19	40	(21.7)	88	83.36
>=65 - <75 years	26	(28.3)	58	109.02	30	(31.3)	61	111.53
>=75 years	5	(50.0)	9	167.46	3	(27.3)	3	45.90
Recovered/resolved with sequelae								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Recovering/resolving								
>=18 - <65 years	9	(4.8)	12	11.03	11	(6.0)	17	16.10
>=65 - <75 years	7	(7.6)	20	37.59	5	(5.2)	5	9.14
>=75 years	0				0			
Recovered/resolved								
>=18 - <65 years	82	(43.4)	154	141.56	85	(46.2)	230	217.87
>=65 - <75 years	56	(60.9)	120	225.56	51	(53.1)	135	246.83
>=75 years	5	(50.0)	6	111.64	6	(54.5)	8	122.41
Unknown								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.12 Adverse events by age group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	267				271			
>=65 - <75 years	20				18			
>=75 years	3				3			
PYE (years)								
>=18 - <65 years	131.27				133.59			
>=65 - <75 years	9.58				9.02			
>=75 years	1.46				1.52			
Events								
>=18 - <65 years	172	(64.4)	453	345.10	173	(63.8)	582	435.68
>=65 - <75 years	14	(70.0)	45	469.74	14	(77.8)	30	332.65
>=75 years	3	(100.0)	9	615.59	3	(100.0)	7	461.51
Serious								
Yes								
>=18 - <65 years	9	(3.4)	13	9.90	7	(2.6)	9	6.74
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	1	(33.3)	1	68.40	0			
No								
>=18 - <65 years	169	(63.3)	440	335.20	170	(62.7)	573	428.94
>=65 - <75 years	14	(70.0)	44	459.30	14	(77.8)	30	332.65
>=75 years	2	(66.7)	8	547.19	3	(100.0)	7	461.51
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
>=18 - <65 years	8	(3.0)	9	6.86	4	(1.5)	5	3.74
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Moderate								
>=18 - <65 years	45	(16.9)	75	57.14	45	(16.6)	78	58.39
>=65 - <75 years	5	(25.0)	14	146.14	5	(27.8)	7	77.62
>=75 years	1	(33.3)	1	68.40	1	(33.3)	4	263.72
Mild								
>=18 - <65 years	154	(57.7)	369	281.11	157	(57.9)	499	373.54
>=65 - <75 years	13	(65.0)	31	323.60	11	(61.1)	23	255.03
>=75 years	2	(66.7)	7	478.79	2	(66.7)	3	197.79
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Related to basal insulin								
Probable								
>=18 - <65 years	16	(6.0)	19	14.47	7	(2.6)	8	5.99
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Possible								
>=18 - <65 years	19	(7.1)	23	17.52	16	(5.9)	40	29.94
>=65 - <75 years	2	(10.0)	2	20.88	1	(5.6)	1	11.09
>=75 years	1	(33.3)	1	68.40	0			
Unlikely								
>=18 - <65 years	161	(60.3)	411	313.10	173	(63.8)	534	399.74
>=65 - <75 years	14	(70.0)	42	438.43	13	(72.2)	29	321.56
>=75 years	3	(100.0)	8	547.19	3	(100.0)	7	461.51
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
No								
>=18 - <65 years	172	(64.4)	453	345.10	173	(63.8)	582	435.68
>=65 - <75 years	14	(70.0)	45	469.74	14	(77.8)	30	332.65
>=75 years	3	(100.0)	9	615.59	3	(100.0)	7	461.51
NA								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Not recovered/not resolved								
>=18 - <65 years	75	(28.1)	115	87.61	75	(27.7)	133	99.56
>=65 - <75 years	10	(50.0)	16	167.02	6	(33.3)	8	88.71
>=75 years	1	(33.3)	3	205.20	2	(66.7)	3	197.79
Recovered/resolved with sequelae								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Recovering/resolving								
>=18 - <65 years	6	(2.2)	6	4.57	4	(1.5)	5	3.74
>=65 - <75 years	0				1	(5.6)	3	33.27
>=75 years	0				0			
Recovered/resolved								
>=18 - <65 years	147	(55.1)	332	252.92	147	(54.2)	442	330.87
>=65 - <75 years	11	(55.0)	29	302.72	12	(66.7)	18	199.59
>=75 years	2	(66.7)	5	341.99	2	(66.7)	4	263.72
Unknown								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.13 Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main- on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	333				332			
>=65 - <75 years	134				144			
>=75 years	25				16			
PYE (years)								
>=18 - <65 years	329.13				329.36			
>=65 - <75 years	132.08				140.33			
>=75 years	24.67				15.35			
Events								
>=18 - <65 years	235	(70.6)	771	234.25	220	(66.3)	759	230.45
>=65 - <75 years	95	(70.9)	357	270.29	104	(72.2)	373	265.80
>=75 years	21	(84.0)	99	401.33	11	(68.8)	30	195.46

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
>=18 - <65 years	5	(1.5)	5	1.52	7	(2.1)	7	2.13
>=65 - <75 years	5	(3.7)	5	3.79	3	(2.1)	3	2.14
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Anaemia								
>=18 - <65 years	1	(0.3)	1	0.30	4	(1.2)	4	1.21
>=65 - <75 years	4	(3.0)	4	3.03	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Blood loss anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Eosinophilia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hypochromic anaemia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Iron deficiency anaemia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Lymphadenopathy								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Polycythaemia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombocytopenia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac disorders								
All								
>=18 - <65 years	14	(4.2)	22	6.68	13	(3.9)	17	5.16
>=65 - <75 years	18	(13.4)	30	22.71	16	(11.1)	20	14.25
>=75 years	5	(20.0)	11	44.59	1	(6.3)	1	6.52

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute coronary syndrome								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute myocardial infarction								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Angina pectoris								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Angina unstable								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Aortic valve calcification								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Aortic valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Arrhythmia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	4	(3.0)	4	3.03	4	(2.8)	4	2.85
>=75 years	3	(12.0)	4	16.22	0			
Atrial flutter								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Atrial thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Atrioventricular block complete								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bradycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Bundle branch block right								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Cardiac dysfunction								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac failure								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Cardiac failure chronic								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Cardiac failure congestive								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Cardiac ventricular thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Chronic coronary syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Coronary artery disease								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	3	(2.2)	3	2.27	2	(1.4)	2	1.43
>=75 years	0				0			
Coronary artery occlusion								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diastolic dysfunction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Left atrial dilatation								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Left ventricular dysfunction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Left ventricular hypertrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Mitral valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Myocardial infarction								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Myocardial ischaemia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Palpitations								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Pericardial effusion								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pericarditis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Sinus arrhythmia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinus bradycardia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus tachycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Supraventricular extrasystoles								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Tachycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Tricuspid valve incompetence								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Ventricular extrasystoles								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	1	(4.0)	1	4.05	0			
Congenital, familial and genetic disorders								
All								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Congenital syphilitic osteochondritis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hydrocele								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Type V hyperlipidaemia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	5	(1.5)	5	1.52	4	(1.2)	4	1.21
>=65 - <75 years	3	(2.2)	3	2.27	5	(3.5)	6	4.28
>=75 years	0				0			
Ear inflammation								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ear pain								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Eustachian tube dysfunction								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoacusis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Presbyacusis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinnitus								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Vertigo								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	3	(2.2)	3	2.27	3	(2.1)	4	2.85
>=75 years	0				0			
Vertigo positional								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
>=18 - <65 years	0				3	(0.9)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	3	(2.1)	3	2.14
>=75 years	0				0			
Goitre								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hyperplasia adrenal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hyperprolactinaemia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperthyroidism								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Thyroid mass								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	12	(3.6)	19	5.77	20	(6.0)	22	6.68
>=65 - <75 years	11	(8.2)	14	10.60	5	(3.5)	10	7.13
>=75 years	2	(8.0)	2	8.11	0			
Acquired epiblepharon								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Asthenopia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Astigmatism								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Blepharitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Cataract								
>=18 - <65 years	4	(1.2)	5	1.52	3	(0.9)	3	0.91
>=65 - <75 years	4	(3.0)	5	3.79	1	(0.7)	2	1.43
>=75 years	1	(4.0)	1	4.05	0			
Conjunctival erosion								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival haemorrhage								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctivitis allergic								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dacryoadenitis acquired								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	2	(0.6)	2	0.61	3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Diplopia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Dry eye								
>=18 - <65 years	0				5	(1.5)	5	1.52
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye discharge								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Eye inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Eye pain								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Glaucoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Normal tension glaucoma								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Ocular hypertension								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Optic disc vascular disorder								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Photophobia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Post thrombotic retinopathy								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Posterior capsule opacification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal aneurysm								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal artery occlusion								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Retinal tear								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vein occlusion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Scintillating scotoma								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Uveitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Visual impairment								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitreous detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Vitreous haemorrhage								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal disorders								
All								
>=18 - <65 years	54	(16.2)	91	27.65	51	(15.4)	80	24.29
>=65 - <75 years	19	(14.2)	30	22.71	21	(14.6)	32	22.80
>=75 years	10	(40.0)	15	60.81	2	(12.5)	2	13.03
Abdominal discomfort								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Abdominal distension								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Abdominal pain								
>=18 - <65 years	3	(0.9)	3	0.91	4	(1.2)	4	1.21
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Abdominal pain lower								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain upper								
>=18 - <65 years	0				4	(1.2)	5	1.52
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Acid peptic disease								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Anal fissure								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Anal pruritus								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Colitis								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Colitis ischaemic								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Colitis microscopic								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Constipation								
>=18 - <65 years	3	(0.9)	3	0.91	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				1	(6.3)	1	6.52
Crohn's disease								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Dental caries								
>=18 - <65 years	4	(1.2)	6	1.82	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	2	(8.0)	2	8.11	0			
Diarrhoea								
>=18 - <65 years	15	(4.5)	21	6.38	16	(4.8)	17	5.16
>=65 - <75 years	7	(5.2)	10	7.57	5	(3.5)	5	3.56
>=75 years	9	(36.0)	12	48.65	0			
Diverticulum								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Diverticulum intestinal								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dry mouth								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Duodenitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Dyspepsia								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Enteritis								
>=18 - <65 years	0				1	(0.3)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Enterocolitis								
>=18 - <65 years	3	(0.9)	4	1.22	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Epigastric discomfort								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Flatulence								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Food poisoning								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Frequent bowel movements								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Gastric disorder								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric polyps								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Gastrointestinal inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Gastrooesophageal reflux disease								
>=18 - <65 years	5	(1.5)	5	1.52	3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	3	(2.1)	3	2.14
>=75 years	0				0			
Haematochezia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Haemorrhoids								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hiatus hernia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hyperaesthesia teeth								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperchlorhydria								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Ileus								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Inguinal hernia								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Intra-abdominal haematoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Irritable bowel syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Large intestine polyp								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	2	0.61
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Loose tooth								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Melaena								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Nausea								
>=18 - <65 years	12	(3.6)	13	3.95	4	(1.2)	5	1.52
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	2	1.43
>=75 years	1	(4.0)	1	4.05	0			
Oral discomfort								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatitis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatitis acute								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pancreatitis chronic								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontal disease								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontal inflammation								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Rectal polyp								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Rectal prolapse								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Stomatitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Tooth disorder								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth impacted								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	8	(2.4)	8	2.43	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Ulcerative gastritis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Umbilical hernia								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Vomiting								
>=18 - <65 years	2	(0.6)	2	0.61	7	(2.1)	8	2.43
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	3	2.14
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	53	(15.9)	78	23.70	53	(16.0)	79	23.99
>=65 - <75 years	18	(13.4)	24	18.17	24	(16.7)	30	21.38
>=75 years	4	(16.0)	12	48.65	1	(6.3)	1	6.52
Asthenia								
>=18 - <65 years	3	(0.9)	3	0.91	2	(0.6)	2	0.61
>=65 - <75 years	0				3	(2.1)	3	2.14
>=75 years	1	(4.0)	1	4.05	0			
Chest discomfort								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Chest pain								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	1	(4.0)	1	4.05	0			
Chills								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Death								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Discomfort								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Drug intolerance								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Early satiety								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Fatigue								
>=18 - <65 years	8	(2.4)	9	2.73	5	(1.5)	5	1.52
>=65 - <75 years	4	(3.0)	4	3.03	0			
>=75 years	1	(4.0)	1	4.05	0			
Feeling abnormal								
>=18 - <65 years	1	(0.3)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Feeling hot								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gait disturbance								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Hunger								
>=18 - <65 years	5	(1.5)	6	1.82	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Implant site pruritus								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Influenza like illness								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site bruising								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Injection site dermatitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Injection site erythema								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	3	0.91
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Injection site haemorrhage								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site hypersensitivity								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site hypertrophy								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site mass								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site pain								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Injection site reaction								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site urticaria								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	3	(0.9)	4	1.22	4	(1.2)	6	1.82
>=65 - <75 years	2	(1.5)	2	1.51	4	(2.8)	4	2.85
>=75 years	0				0			
Medical device site bruise								
>=18 - <65 years	2	(0.6)	3	0.91	0			
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	1	(0.3)	4	1.22	8	(2.4)	14	4.25
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site eczema								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Medical device site haematoma								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site haemorrhage								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Medical device site hypersensitivity								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site inflammation								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pruritus								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	3	2.27	1	(0.7)	1	0.71
>=75 years	0				0			
Non-cardiac chest pain								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Oedema peripheral								
>=18 - <65 years	3	(0.9)	3	0.91	4	(1.2)	5	1.52

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Pain								
>=18 - <65 years	2	(0.6)	2	0.61	4	(1.2)	4	1.21
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	1	(4.0)	1	4.05	0			
Peripheral swelling								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Procedural failure								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	10	(3.0)	11	3.34	14	(4.2)	15	4.55
>=65 - <75 years	4	(3.0)	4	3.03	7	(4.9)	7	4.99
>=75 years	3	(12.0)	3	12.16	0			
Swelling								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Thirst								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	1	(4.0)	2	8.11	0			
Vaccination site reaction								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatobiliary disorders								
All								
>=18 - <65 years	7	(2.1)	9	2.73	6	(1.8)	7	2.13
>=65 - <75 years	2	(1.5)	3	2.27	0			
>=75 years	0				0			
Cholelithiasis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gallbladder cholesterolosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Hepatic cirrhosis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic cyst								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic function abnormal								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic steatosis								
>=18 - <65 years	4	(1.2)	4	1.22	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Hypertransaminasaemia								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Liver disorder								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Non-alcoholic steatohepatitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nonalcoholic fatty liver disease								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Steatohepatitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
>=18 - <65 years	2	(0.6)	3	0.91	3	(0.9)	4	1.21
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Allergy to arthropod bite								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Immunisation reaction								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Infections and infestations								
All								
>=18 - <65 years	112	(33.6)	178	54.08	137	(41.3)	207	62.85
>=65 - <75 years	47	(35.1)	71	53.76	49	(34.0)	67	47.75
>=75 years	10	(40.0)	14	56.75	7	(43.8)	13	84.70
Abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Acarodermatitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Acute sinusitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Anal abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Asymptomatic COVID-19								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bacterial infection								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Balanitis candida								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Body tinea								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast abscess								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast cellulitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	5	(1.5)	5	1.52	3	(0.9)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Candida infection								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cellulitis								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Chlamydial infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Chronic hepatitis C								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic sinusitis								
>=18 - <65 years	0				3	(0.9)	3	0.91
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chronic tonsillitis								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Clostridium difficile infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Coronavirus infection								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	4	1.21
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
COVID-19								
>=18 - <65 years	37	(11.1)	37	11.24	49	(14.8)	50	15.18
>=65 - <75 years	10	(7.5)	10	7.57	9	(6.3)	9	6.41
>=75 years	2	(8.0)	2	8.11	3	(18.8)	3	19.55
COVID-19 pneumonia								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Cystitis								
>=18 - <65 years	3	(0.9)	3	0.91	5	(1.5)	6	1.82
>=65 - <75 years	2	(1.5)	3	2.27	2	(1.4)	2	1.43
>=75 years	0				1	(6.3)	1	6.52
Dermatophytosis of nail								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Diverticulitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				1	(6.3)	1	6.52
Ear infection								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Empyema								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endophthalmitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Epididymitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Erysipelas								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Escherichia urinary tract infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Eye infection bacterial								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Folliculitis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal balanitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal infection								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Furuncle								
>=18 - <65 years	1	(0.3)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis								
>=18 - <65 years	4	(1.2)	4	1.22	3	(0.9)	3	0.91
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Gastroenteritis norovirus								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis viral								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Gastrointestinal infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Genital infection fungal								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Giardiasis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Gingivitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Helicobacter gastritis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Helicobacter infection								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes dermatitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes simplex								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Herpes virus infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Herpes zoster								
>=18 - <65 years	3	(0.9)	3	0.91	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	3	(2.1)	3	2.14
>=75 years	0				1	(6.3)	1	6.52

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hordeolum								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Infected bite								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Influenza								
>=18 - <65 years	0				3	(0.9)	3	0.91
>=65 - <75 years	0				0			
>=75 years	0				0			
Labyrinthitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngitis								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngopharyngitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Localised infection								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Lower respiratory tract infection								
>=18 - <65 years	4	(1.2)	4	1.22	1	(0.3)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Lyme disease								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Mastitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nail infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasopharyngitis								
>=18 - <65 years	19	(5.7)	22	6.68	26	(7.8)	29	8.81
>=65 - <75 years	11	(8.2)	14	10.60	7	(4.9)	7	4.99
>=75 years	0				1	(6.3)	1	6.52
Onychomycosis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oophoritis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral herpes								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal candidiasis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteomyelitis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Otitis externa								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media acute								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media chronic								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Parotitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peri-implantitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Pericoronitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontitis								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Pharyngitis								
>=18 - <65 years	10	(3.0)	12	3.65	8	(2.4)	10	3.04
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Pharyngotonsillitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	2	13.03
Pneumonia								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	3	(2.2)	3	2.27	0			
>=75 years	0				0			
Post procedural infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pulpitis dental								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Purulence								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory syncytial virus infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Respiratory tract infection								
>=18 - <65 years	3	(0.9)	3	0.91	2	(0.6)	2	0.61
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory tract infection viral								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Rhinitis								
>=18 - <65 years	4	(1.2)	4	1.22	3	(0.9)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Rotavirus infection								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Salpingitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Sepsis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	3	(0.9)	4	1.22	5	(1.5)	7	2.13
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Skin bacterial infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Skin infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Subcutaneous abscess								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinea infection								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tonsillitis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth abscess								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	2	(1.5)	2	1.51	2	(1.4)	2	1.43
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				1	(6.3)	1	6.52
Tracheitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper respiratory tract infection								
>=18 - <65 years	16	(4.8)	21	6.38	6	(1.8)	6	1.82
>=65 - <75 years	5	(3.7)	7	5.30	7	(4.9)	8	5.70
>=75 years	2	(8.0)	2	8.11	0			
Urethritis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary tract infection								
>=18 - <65 years	5	(1.5)	5	1.52	11	(3.3)	11	3.34
>=65 - <75 years	1	(0.7)	1	0.76	5	(3.5)	6	4.28
>=75 years	1	(4.0)	1	4.05	0			
Vaginal infection								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Varicella								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral infection								
>=18 - <65 years	3	(0.9)	3	0.91	2	(0.6)	2	0.61
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Viral pharyngitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral upper respiratory tract infection								
>=18 - <65 years	0				3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal candidiasis								
>=18 - <65 years	2	(0.6)	3	0.91	4	(1.2)	4	1.21
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal mycotic infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Injury, poisoning and procedural complications								
All								
>=18 - <65 years	39	(11.7)	43	13.06	28	(8.4)	38	11.54
>=65 - <75 years	17	(12.7)	18	13.63	12	(8.3)	14	9.98
>=75 years	4	(16.0)	4	16.22	0			
Accidental overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Animal bite								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Ankle fracture								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod sting								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Bone contusion								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Burn oral cavity								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Burns first degree								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervical vertebral fracture								
>=18 - <65 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Chillblains								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Contusion								
>=18 - <65 years	3	(0.9)	4	1.22	4	(1.2)	4	1.21
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Deafness traumatic								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Endotracheal intubation complication								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye injury								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Fall								
>=18 - <65 years	4	(1.2)	4	1.22	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Fibula fracture								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Foot fracture								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hand fracture								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Heat illness								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	2	0.61
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hip fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injury								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint injury								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Ligament sprain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Lower limb fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Meniscus injury								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle strain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Post procedural fistula								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Post procedural haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Post procedural hypothyroidism								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Post procedural stroke								

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Post procedural swelling								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Procedural pain								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Radius fracture								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Rib fracture								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Scar								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Skin laceration								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Soft tissue injury								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Thermal burn								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth fracture								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Traumatic haematoma								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Underdose								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	7	(2.1)	7	2.13	9	(2.7)	14	4.25
>=65 - <75 years	2	(1.5)	2	1.51	4	(2.8)	5	3.56
>=75 years	1	(4.0)	1	4.05	0			
Wound								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Wrist fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Investigations								
All								
>=18 - <65 years	16	(4.8)	17	5.17	15	(4.5)	16	4.86
>=65 - <75 years	3	(2.2)	3	2.27	5	(3.5)	5	3.56
>=75 years	2	(8.0)	4	16.22	1	(6.3)	1	6.52
Alanine aminotransferase increased								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Aspartate aminotransferase increased								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood cholesterol increased								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood creatine increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Blood creatine phosphokinase increased								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood glucose increased								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Blood pressure decreased								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood pressure increased								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Blood triglycerides increased								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Body temperature increased								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac stress test abnormal								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram repolarisation abnormality								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Glycosylated haemoglobin increased								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoglobin decreased								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic enzyme increased								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
International normalised ratio abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
International normalised ratio decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
International normalised ratio increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	2	8.11	0			
Lipids increased								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Red blood cell count decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
SARS-CoV-2 test positive								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Transferrin saturation decreased								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight decreased								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Weight increased								
>=18 - <65 years	5	(1.5)	5	1.52	8	(2.4)	8	2.43
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Metabolism and nutrition disorders								
All								
>=18 - <65 years	27	(8.1)	30	9.11	26	(7.8)	33	10.02
>=65 - <75 years	11	(8.2)	14	10.60	19	(13.2)	26	18.53
>=75 years	3	(12.0)	3	12.16	1	(6.3)	1	6.52
Appetite disorder								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Decreased appetite								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Dehydration								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Diabetes mellitus								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Dyslipidaemia								
>=18 - <65 years	8	(2.4)	8	2.43	5	(1.5)	5	1.52
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Electrolyte imbalance								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Fluid retention								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gout								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	2	1.51	3	(2.1)	3	2.14
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Hyperglycaemia								
>=18 - <65 years	0				6	(1.8)	6	1.82
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperkalaemia								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	3	2.27	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Hyperlipidaemia								
>=18 - <65 years	4	(1.2)	4	1.22	1	(0.3)	1	0.30
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Hypertriglyceridaemia								
>=18 - <65 years	4	(1.2)	4	1.22	3	(0.9)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Hyperuricaemia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemia								
>=18 - <65 years	4	(1.2)	5	1.52	5	(1.5)	10	3.04
>=65 - <75 years	0				4	(2.8)	10	7.13
>=75 years	0				0			
Hypokalaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Increased appetite								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Iron deficiency								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Malnutrition								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Metabolic disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Obesity								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitamin D deficiency								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Zinc deficiency								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	70	(21.0)	103	31.29	56	(16.9)	82	24.90
>=65 - <75 years	24	(17.9)	41	31.04	34	(23.6)	47	33.49
>=75 years	5	(20.0)	12	48.65	2	(12.5)	4	26.06
Arthralgia								
>=18 - <65 years	15	(4.5)	17	5.17	9	(2.7)	10	3.04
>=65 - <75 years	5	(3.7)	7	5.30	6	(4.2)	7	4.99

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	3	(12.0)	3	12.16	2	(12.5)	2	13.03
Arthritis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Axillary mass								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Back disorder								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	16	(4.8)	17	5.17	15	(4.5)	16	4.86
>=65 - <75 years	10	(7.5)	11	8.33	8	(5.6)	8	5.70
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Bone cyst								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bursitis								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	3	0.91
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervical spinal stenosis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Chondropathy								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Coccydynia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Costochondritis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dupuytren's contracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Exostosis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibromyalgia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Fistula								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Flank pain								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Groin pain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Intervertebral disc disorder								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Intervertebral disc protrusion								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	4	1.21
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	1	(4.0)	2	8.11	0			
Joint effusion								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint swelling								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Limb deformity								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Lumbar spinal stenosis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Mastication disorder								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(0.7)	2	1.43
>=75 years	0				0			
Muscle contracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	3	(0.9)	3	0.91	4	(1.2)	4	1.21
>=65 - <75 years	4	(3.0)	4	3.03	0			
>=75 years	1	(4.0)	1	4.05	0			
Muscular weakness								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal chest pain								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Musculoskeletal pain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal stiffness								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Myalgia								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Myositis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Neck pain								
>=18 - <65 years	4	(1.2)	4	1.22	5	(1.5)	5	1.52
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	10	(3.0)	12	3.65	4	(1.2)	5	1.52
>=65 - <75 years	1	(0.7)	1	0.76	5	(3.5)	5	3.56
>=75 years	1	(4.0)	1	4.05	0			
Osteochondrosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Osteopenia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Pain in extremity								
>=18 - <65 years	9	(2.7)	9	2.73	7	(2.1)	8	2.43
>=65 - <75 years	6	(4.5)	7	5.30	4	(2.8)	6	4.28
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	6	(1.8)	6	1.82	2	(0.6)	2	0.61
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				1	(6.3)	1	6.52
Plantar fasciitis								
>=18 - <65 years	3	(0.9)	4	1.22	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Polyarthritis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Rotator cuff syndrome								
>=18 - <65 years	3	(0.9)	3	0.91	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Spinal osteoarthritis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	1	(4.0)	1	4.05	0			
Spinal pain								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Spinal stenosis								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Synovial cyst								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Tendonitis								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Tenosynovitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	3	0.91
>=65 - <75 years	0				3	(2.1)	3	2.14
>=75 years	0				0			
Tenosynovitis stenosans								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	0				2	(0.6)	4	1.21
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Vertebral osteophyte								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	6	(1.8)	6	1.82	2	(0.6)	3	0.91
>=65 - <75 years	2	(1.5)	2	1.51	3	(2.1)	6	4.28
>=75 years	3	(12.0)	5	20.27	0			
Acrochordon								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Basal cell carcinoma								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Colon cancer								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Dysplastic naevus								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Glioblastoma multiforme								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Haemangioma of liver								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatocellular carcinoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Malignant melanoma in situ								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Metastases to liver								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Neoplasm skin								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral fibroma								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian cancer metastatic								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pancreatic neoplasm								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Prostate cancer								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Renal cell carcinoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Salivary gland neoplasm								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Seborrhoeic keratosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	1	(4.0)	2	8.11	0			
Uterine leiomyoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Nervous system disorders								
All								
>=18 - <65 years	40	(12.0)	52	15.80	42	(12.7)	57	17.31
>=65 - <75 years	19	(14.2)	29	21.96	23	(16.0)	26	18.53
>=75 years	6	(24.0)	6	24.32	2	(12.5)	2	13.03
Ageusia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Anosmia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Balance disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Brain injury								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Burning sensation								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	1	(4.0)	1	4.05	0			
Carotid arteriosclerosis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Carpal tunnel syndrome								
>=18 - <65 years	3	(0.9)	3	0.91	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Cerebral atrophy								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebral haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cerebrovascular disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Cervical radiculopathy								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Dizziness								
>=18 - <65 years	8	(2.4)	8	2.43	8	(2.4)	9	2.73
>=65 - <75 years	4	(3.0)	8	6.06	6	(4.2)	6	4.28
>=75 years	0				0			
Dizziness postural								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Dysgeusia								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Headache								
>=18 - <65 years	11	(3.3)	13	3.95	13	(3.9)	18	5.47
>=65 - <75 years	3	(2.2)	3	2.27	2	(1.4)	4	2.85
>=75 years	2	(8.0)	2	8.11	2	(12.5)	2	13.03
Hypoaesthesia								
>=18 - <65 years	3	(0.9)	5	1.52	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	1	(0.7)	2	1.43
>=75 years	0				0			
Lethargy								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Lumbar radiculopathy								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	3	0.91
>=65 - <75 years	0				0			
>=75 years	0				0			
Memory impairment								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Mental impairment								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Migraine								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Neuroglycopenia								
>=18 - <65 years	0				1	(0.3)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Neuropathy peripheral								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Paraesthesia								
>=18 - <65 years	3	(0.9)	3	0.91	3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Parkinsonian gait								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Post herpetic neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Presyncope								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Sciatica								
>=18 - <65 years	2	(0.6)	2	0.61	5	(1.5)	6	1.82
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Somnolence								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Syncope								
>=18 - <65 years	4	(1.2)	4	1.22	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tension headache								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Thrombotic stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Transient ischaemic attack								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Tremor								
>=18 - <65 years	4	(1.2)	4	1.22	0			
>=65 - <75 years	1	(0.7)	2	1.51	1	(0.7)	1	0.71
>=75 years	0				0			
Trigeminal neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Vertebral artery occlusion								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
>=18 - <65 years	7	(2.1)	7	2.13	7	(2.1)	7	2.13
>=65 - <75 years	7	(5.2)	8	6.06	3	(2.1)	3	2.14
>=75 years	1	(4.0)	1	4.05	0			
Anxiety								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Bruxism								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Depressed mood								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depression								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Insomnia								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	3	(2.2)	3	2.27	1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Mood swings								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Nightmare								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Persistent depressive disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Renal and urinary disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	6	(1.8)	8	2.43	9	(2.7)	11	3.34
>=65 - <75 years	5	(3.7)	7	5.30	8	(5.6)	8	5.70
>=75 years	3	(12.0)	3	12.16	3	(18.8)	3	19.55
Acute kidney injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Calculus urinary								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Chronic kidney disease								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Diabetic nephropathy								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	1	(4.0)	1	4.05	0			
Dysuria								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				1	(6.3)	1	6.52
Haematuria								
>=18 - <65 years	0				0			
>=65 - <75 years	0				3	(2.1)	3	2.14
>=75 years	0				0			
Microalbuminuria								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nephrolithiasis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Nocturia								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	1	(4.0)	1	4.05	0			
Pollakiuria								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pyelocaliectasis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Renal colic								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal impairment								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	6.52
Ureterolithiasis								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Urinary incontinence								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary retention								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary tract obstruction								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Urine odour abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Reproductive system and breast disorders								
All								
>=18 - <65 years	6	(1.8)	6	1.82	4	(1.2)	5	1.52
>=65 - <75 years	4	(3.0)	4	3.03	3	(2.1)	4	2.85
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrophic vulvovaginitis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign prostatic hyperplasia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Breast mass								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Breast pain								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Erectile dysfunction								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Galactorrhoea								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Menopausal symptoms								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian cyst								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Penile rash								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	2	1.43
>=75 years	0				0			
Pruritus genital								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Uterine polyp								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Uterine prolapse								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal dryness								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal pruritus								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	27	(8.1)	35	10.63	25	(7.5)	33	10.02
>=65 - <75 years	16	(11.9)	22	16.66	13	(9.0)	19	13.54
>=75 years	2	(8.0)	2	8.11	0			
Acquired diaphragmatic eventration								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute pulmonary oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Acute respiratory failure								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Allergic bronchitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Asthma								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchiectasis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis chronic								
>=18 - <65 years	0				1	(0.3)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic obstructive pulmonary disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Cough								
>=18 - <65 years	7	(2.1)	7	2.13	4	(1.2)	4	1.21
>=65 - <75 years	3	(2.2)	3	2.27	4	(2.8)	5	3.56
>=75 years	0				0			
Dyspnoea								
>=18 - <65 years	0				3	(0.9)	3	0.91
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Dyspnoea exertional								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Emphysema								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Epistaxis								
>=18 - <65 years	0				1	(0.3)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoptysis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Interstitial lung disease								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Laryngeal cyst								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasal congestion								
>=18 - <65 years	2	(0.6)	2	0.61	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	1	(4.0)	1	4.05	0			
Nasal dryness								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal turbinate hypertrophy								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	6	(1.8)	6	1.82	4	(1.2)	4	1.21
>=65 - <75 years	4	(3.0)	5	3.79	3	(2.1)	4	2.85
>=75 years	0				0			
Paranasal sinus discomfort								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pleural effusion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Pleuritic pain								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Productive cough								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary embolism								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary fibrosis								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary mass								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Respiratory disorder								
>=18 - <65 years	1	(0.3)	1	0.30	3	(0.9)	3	0.91
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory failure								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinitis allergic								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				1	(0.3)	5	1.52
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	4	(1.2)	4	1.22	1	(0.3)	1	0.30
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Sinus congestion								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	2	1.51	0			
>=75 years	0				0			
Sinus pain								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	2	1.51	0			
>=75 years	0				0			
Sleep apnoea syndrome								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			
Sneezing								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Throat irritation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Upper-airway cough syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Skin and subcutaneous tissue disorders								
All								
>=18 - <65 years	27	(8.1)	29	8.81	24	(7.2)	31	9.41
>=65 - <75 years	13	(9.7)	13	9.84	18	(12.5)	24	17.10
>=75 years	2	(8.0)	2	8.11	0			
Actinic keratosis								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Alopecia								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	2	(1.5)	2	1.51	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alopecia areata								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Angioedema								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Asteatosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Blister								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Cold sweat								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Cold urticaria								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermal cyst								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				3	(2.1)	3	2.14
>=75 years	0				0			
Dermatitis allergic								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis contact								
>=18 - <65 years	4	(1.2)	5	1.52	3	(0.9)	3	0.91
>=65 - <75 years	1	(0.7)	1	0.76	3	(2.1)	3	2.14
>=75 years	0				0			
Diabetic foot								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Drug eruption								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Dry skin								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Ecchymosis								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema								
>=18 - <65 years	5	(1.5)	5	1.52	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Granuloma annulare								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhage subcutaneous								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hyperhidrosis								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperkeratosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Ingrowing nail								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Lentigo								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipodystrophy acquired								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipohypertrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Macule								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Miliaria								
>=18 - <65 years	0				4	(1.2)	4	1.21
>=65 - <75 years	0				0			
>=75 years	0				0			
Myxoid cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Night sweats								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Pruritus								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	2	(1.5)	2	1.51	2	(1.4)	2	1.43
>=75 years	0				0			
Psoriasis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Purpura								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Rash								
>=18 - <65 years	1	(0.3)	1	0.30	4	(1.2)	4	1.21
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Skin exfoliation								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Skin fissures								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin irritation								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Skin lesion								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Skin ulcer								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	0				2	(1.4)	2	1.43
>=75 years	0				0			
Urticaria contact								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Urticaria thermal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Surgical and medical procedures								
All								
>=18 - <65 years	1	(0.3)	1	0.30	2	(0.6)	2	0.61
>=65 - <75 years	0				0			
>=75 years	0				0			
Knee operation								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Large intestinal polypectomy								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Removal of foreign body								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Vascular disorders								
All								
>=18 - <65 years	20	(6.0)	23	6.99	7	(2.1)	10	3.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	10	(7.5)	12	9.09	17	(11.8)	18	12.83
>=75 years	2	(8.0)	2	8.11	1	(6.3)	1	6.52
Aortic arteriosclerosis								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	4.05	0			
Aortic stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Arteriosclerosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	2	(1.4)	2	1.43
>=75 years	0				0			
Blood pressure inadequately controlled								
>=18 - <65 years	0				1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Brachiocephalic arteriosclerosis								
>=18 - <65 years	0				2	(0.6)	2	0.61
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Flushing								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haematoma								
>=18 - <65 years	1	(0.3)	1	0.30	1	(0.3)	1	0.30
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertension								
>=18 - <65 years	9	(2.7)	9	2.73	2	(0.6)	3	0.91
>=65 - <75 years	3	(2.2)	3	2.27	7	(4.9)	7	4.99
>=75 years	1	(4.0)	1	4.05	1	(6.3)	1	6.52
Hypertensive crisis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Hypertensive urgency								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Hypotension								
>=18 - <65 years	2	(0.6)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Iliac artery stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Intermittent claudication								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Macroangiopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Peripheral arterial occlusive disease								
>=18 - <65 years	1	(0.3)	2	0.61	1	(0.3)	1	0.30
>=65 - <75 years	0				1	(0.7)	1	0.71
>=75 years	0				0			
Peripheral artery occlusion								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral artery stenosis								
>=18 - <65 years	1	(0.3)	2	0.61	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral coldness								
>=18 - <65 years	2	(0.6)	2	0.61	0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Peripheral vascular disorder								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral venous disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			
Superficial vein thrombosis								
>=18 - <65 years	1	(0.3)	1	0.30	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	0			
>=75 years	0				0			
Varicose vein								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.76	1	(0.7)	1	0.71
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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7.16.14 Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	144				149			
>=65 - <75 years	99				99			
>=75 years	19				15			
PYE (years)								
>=18 - <65 years	85.31				87.79			
>=65 - <75 years	58.97				56.04			
>=75 years	10.97				8.94			
Events								
>=18 - <65 years	93	(64.6)	292	342.28	83	(55.7)	211	240.34
>=65 - <75 years	54	(54.5)	148	251.00	43	(43.4)	100	178.45
>=75 years	14	(73.7)	26	237.00	8	(53.3)	17	190.12
Blood and lymphatic system disorders								
All								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	3	5.09	0			
>=75 years	0				0			
Anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	3	5.09	0			
>=75 years	0				0			
Thrombocytosis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
>=18 - <65 years	3	(2.1)	4	4.69	1	(0.7)	1	1.14
>=65 - <75 years	2	(2.0)	3	5.09	1	(1.0)	1	1.78
>=75 years	0				0			
Acute myocardial infarction								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bradycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Cardiac failure congestive								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Cardiac flutter								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Coronary artery disease								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Myocardial infarction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Supraventricular tachycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	2	(1.4)	2	2.34	2	(1.3)	2	2.28
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	1	(5.3)	1	9.12	1	(6.7)	1	11.18
Deafness unilateral								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Ear pain								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoacusis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinnitus								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Vertigo								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	1	(5.3)	1	9.12	1	(6.7)	1	11.18
Endocrine disorders								
All								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				1	(6.7)	1	11.18

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Adrenocortical insufficiency acute								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.7)	1	11.18
Inappropriate antidiuretic hormone secretion								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	15	(10.4)	18	21.10	19	(12.8)	22	25.06
>=65 - <75 years	10	(10.1)	11	18.66	5	(5.1)	7	12.49
>=75 years	2	(10.5)	2	18.23	1	(6.7)	1	11.18
Astigmatism								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Cataract								
>=18 - <65 years	2	(1.4)	2	2.34	4	(2.7)	4	4.56
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract nuclear								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	2	(1.4)	2	2.34	1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	6	(4.2)	7	8.21	13	(8.7)	14	15.95
>=65 - <75 years	3	(3.0)	3	5.09	2	(2.0)	2	3.57
>=75 years	1	(5.3)	1	9.12	1	(6.7)	1	11.18
Dry age-related macular degeneration								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dry eye								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Epiretinal membrane								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Eye irritation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Glaucoma								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Lacrimation increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Myopia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Non-proliferative retinopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Ocular hyperaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Ocular hypertension								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Presbyopia								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Retinal exudates								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal haemorrhage								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vein occlusion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Visual acuity reduced								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Vitreous haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Gastrointestinal disorders								
All								
>=18 - <65 years	24	(16.7)	37	43.37	24	(16.1)	31	35.31
>=65 - <75 years	11	(11.1)	20	33.92	8	(8.1)	11	19.63
>=75 years	3	(15.8)	3	27.35	0			
Abdominal pain								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Abdominal pain lower								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Abdominal pain upper								
>=18 - <65 years	1	(0.7)	3	3.52	3	(2.0)	3	3.42
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	1	(5.3)	1	9.12	0			
Constipation								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	3	(3.0)	6	10.18	0			
>=75 years	0				0			
Dental caries								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Diarrhoea								
>=18 - <65 years	9	(6.3)	12	14.07	7	(4.7)	7	7.97
>=65 - <75 years	4	(4.0)	4	6.78	2	(2.0)	2	3.57
>=75 years	1	(5.3)	1	9.12	0			
Diverticulum								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Dyspepsia								
>=18 - <65 years	3	(2.1)	3	3.52	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Flatulence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Food poisoning								
>=18 - <65 years	0				1	(0.7)	2	2.28
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Gastric dysplasia								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric mucosal hypertrophy								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric polyps								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastritis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrointestinal angiodysplasia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Gastrooesophageal reflux disease								
>=18 - <65 years	1	(0.7)	1	1.17	2	(1.3)	2	2.28
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingival bleeding								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Haemorrhoids								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Hiatus hernia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Hyperaesthesia teeth								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Intra-abdominal haematoma								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Large intestine polyp								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Nausea								
>=18 - <65 years	6	(4.2)	6	7.03	3	(2.0)	3	3.42
>=65 - <75 years	1	(1.0)	1	1.70	3	(3.0)	3	5.35
>=75 years	0				0			
Pancreatic pseudocyst								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Periodontal disease								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Tongue rough								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	1	(0.7)	1	1.17	2	(1.3)	4	4.56
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Vomiting								
>=18 - <65 years	3	(2.1)	3	3.52	2	(1.3)	2	2.28
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	19	(13.2)	26	30.48	12	(8.1)	14	15.95
>=65 - <75 years	6	(6.1)	10	16.96	5	(5.1)	5	8.92
>=75 years	0				2	(13.3)	2	22.37
Asthenia								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Chest discomfort								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chest pain								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Chills								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Condition aggravated								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Fatigue								
>=18 - <65 years	2	(1.4)	3	3.52	3	(2.0)	3	3.42
>=65 - <75 years	0				0			
>=75 years	0				0			
Hunger								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Influenza like illness								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site reaction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Injection site swelling								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	2	2.28
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Medical device site bruise								
>=18 - <65 years	1	(0.7)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site erythema								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pruritus								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site rash								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Oedema peripheral								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Pain								
>=18 - <65 years	2	(1.4)	2	2.34	1	(0.7)	1	1.14

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	5	(3.5)	5	5.86	5	(3.4)	5	5.70
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	2	(2.0)	3	5.09	0			
>=75 years	0				2	(13.3)	2	22.37
Hepatobiliary disorders								
All								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	2	(2.0)	2	3.39	0			
>=75 years	0				0			
Alcoholic liver disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Gallbladder polyp								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Hepatic cirrhosis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
>=18 - <65 years	2	(1.4)	2	2.34	3	(2.0)	3	3.42
>=65 - <75 years	0				2	(2.0)	2	3.57
>=75 years	0				0			
Allergy to arthropod bite								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Allergy to arthropod sting								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Anaphylactic reaction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	1	(0.7)	1	1.17	2	(1.3)	2	2.28
>=65 - <75 years	0				0			
>=75 years	0				0			
Infections and infestations								
All								
>=18 - <65 years	44	(30.6)	61	71.50	31	(20.8)	43	48.98
>=65 - <75 years	26	(26.3)	30	50.88	17	(17.2)	22	39.26
>=75 years	6	(31.6)	7	63.81	1	(6.7)	1	11.18
Abscess limb								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Anal abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Campylobacter gastroenteritis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cellulitis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	2	2.28
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
COVID-19								
>=18 - <65 years	3	(2.1)	3	3.52	5	(3.4)	5	5.70
>=65 - <75 years	5	(5.1)	5	8.48	2	(2.0)	2	3.57
>=75 years	1	(5.3)	1	9.12	0			
COVID-19 pneumonia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	1	(5.3)	1	9.12	0			
Cystitis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	2	3.57
>=75 years	0				0			
Ear infection								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Enteritis infectious								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Eye infection								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Folliculitis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal infection								
>=18 - <65 years	1	(0.7)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal skin infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis								
>=18 - <65 years	3	(2.1)	3	3.52	2	(1.3)	2	2.28
>=65 - <75 years	2	(2.0)	2	3.39	0			
>=75 years	0				0			
Gastrointestinal infection								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingivitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.7)	1	11.18
Helicobacter infection								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes zoster								
>=18 - <65 years	0				2	(1.3)	2	2.28
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Influenza								
>=18 - <65 years	1	(0.7)	1	1.17	3	(2.0)	4	4.56
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Kidney infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Localised infection								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasopharyngitis								
>=18 - <65 years	18	(12.5)	24	28.13	7	(4.7)	10	11.39
>=65 - <75 years	4	(4.0)	4	6.78	3	(3.0)	4	7.14
>=75 years	0				0			
Onychomycosis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media								
>=18 - <65 years	0				0			
>=65 - <75 years	3	(3.0)	3	5.09	1	(1.0)	1	1.78
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paraspinal abscess								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peritonsillar abscess								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumonia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Pulpitis dental								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Pustule								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Rhinitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	3	5.35
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	2	(1.4)	2	2.34	2	(1.3)	2	2.28
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Soft tissue infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Subcutaneous abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Tinea pedis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Tinea versicolour								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tonsillitis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth abscess								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	1	(0.7)	2	2.34	2	(1.3)	2	2.28
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Upper respiratory tract infection								
>=18 - <65 years	6	(4.2)	9	10.55	4	(2.7)	4	4.56
>=65 - <75 years	2	(2.0)	2	3.39	0			
>=75 years	0				0			
Urinary tract infection								
>=18 - <65 years	2	(1.4)	2	2.34	1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	2	(2.0)	2	3.57
>=75 years	1	(5.3)	2	18.23	0			
Vaginal infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Varicella zoster virus infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Vulvitis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal candidiasis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Wound infection								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injury, poisoning and procedural complications								
All								
>=18 - <65 years	13	(9.0)	22	25.79	13	(8.7)	14	15.95
>=65 - <75 years	9	(9.1)	12	20.35	6	(6.1)	9	16.06
>=75 years	5	(26.3)	5	45.58	3	(20.0)	3	33.55

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Accidental overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	3	(3.0)	3	5.09	0			
>=75 years	1	(5.3)	1	9.12	0			
Arthropod bite								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Arthropod sting								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Bone contusion								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Contusion								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Craniocerebral injury								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Face injury								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Facial bones fracture								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fall								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	3	(3.0)	3	5.09	2	(2.0)	2	3.57
>=75 years	0				0			
Foot fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Hand fracture								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Heat illness								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Intentional overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Joint injury								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Ligament sprain								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	2	3.57
>=75 years	0				0			
Muscle contusion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.7)	1	11.18
Muscle injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Overdose								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Rib fracture								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Road traffic accident								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	2	(1.4)	2	2.34	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin laceration								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	2	(10.5)	2	18.23	0			
Stab wound								
>=18 - <65 years	0				1	(0.7)	1	1.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Subcutaneous haematoma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Tendon injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Tendon rupture								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Thermal burn								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tibia fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.7)	1	11.18
Underdose								
>=18 - <65 years	1	(0.7)	1	1.17	3	(2.0)	3	3.42
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	3	(2.1)	7	8.21	2	(1.3)	2	2.28
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	1	(6.7)	1	11.18
Wound								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Wrist fracture								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
>=18 - <65 years	4	(2.8)	4	4.69	2	(1.3)	3	3.42
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	1	(5.3)	1	9.12	0			
Alanine aminotransferase increased								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood creatinine increased								
>=18 - <65 years	3	(2.1)	3	3.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood potassium increased								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Intraocular pressure increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Liver function test abnormal								
>=18 - <65 years	0				1	(0.7)	2	2.28
>=65 - <75 years	0				0			
>=75 years	0				0			
SARS-CoV-2 test positive								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
>=18 - <65 years	5	(3.5)	5	5.86	4	(2.7)	4	4.56
>=65 - <75 years	1	(1.0)	1	1.70	6	(6.1)	7	12.49
>=75 years	1	(5.3)	1	9.12	1	(6.7)	5	55.92
Abnormal weight gain								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Hyperammonaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Hyperglycaemia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				2	(2.0)	2	3.57
>=75 years	1	(5.3)	1	9.12	0			
Hyperkalaemia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Hyperlipidaemia								
>=18 - <65 years	1	(0.7)	1	1.17	3	(2.0)	3	3.42
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperuricaemia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemia								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	2	3.57
>=75 years	0				1	(6.7)	5	55.92
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	25	(17.4)	36	42.20	21	(14.1)	35	39.87
>=65 - <75 years	12	(12.1)	23	39.01	6	(6.1)	8	14.28
>=75 years	1	(5.3)	1	9.12	2	(13.3)	2	22.37

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthralgia								
>=18 - <65 years	2	(1.4)	3	3.52	8	(5.4)	10	11.39
>=65 - <75 years	4	(4.0)	4	6.78	1	(1.0)	2	3.57
>=75 years	0				1	(6.7)	1	11.18
Arthritis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Axillary mass								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	5	(3.5)	5	5.86	8	(5.4)	10	11.39
>=65 - <75 years	2	(2.0)	2	3.39	2	(2.0)	2	3.57
>=75 years	0				1	(6.7)	1	11.18
Bursitis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Flank pain								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Intervertebral disc disorder								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Intervertebral disc protrusion								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	8	(5.6)	10	11.72	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Musculoskeletal stiffness								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Myalgia								
>=18 - <65 years	2	(1.4)	2	2.34	2	(1.3)	2	2.28
>=65 - <75 years	2	(2.0)	2	3.39	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteoporosis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Pain in extremity								
>=18 - <65 years	2	(1.4)	2	2.34	3	(2.0)	3	3.42
>=65 - <75 years	1	(1.0)	1	1.70	2	(2.0)	3	5.35
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Plantar fasciitis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Polymyalgia rheumatica								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	3	3.42
>=65 - <75 years	0				0			
>=75 years	0				0			
Rheumatoid arthritis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Rotator cuff syndrome								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Soft tissue swelling								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	3	5.09	0			
>=75 years	0				0			
Spinal stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.0)	4	6.78	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendonitis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	3	5.09	0			
>=75 years	0				0			
Tenosynovitis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	2	(1.4)	2	2.34	1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	3	(3.0)	3	5.35
>=75 years	0				0			
Breast cancer								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic myeloid leukaemia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Colon adenoma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Colon cancer stage II								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Gastric cancer								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphangioma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Pancreatic carcinoma metastatic								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nervous system disorders								
All								
>=18 - <65 years	19	(13.2)	29	33.99	17	(11.4)	22	25.06
>=65 - <75 years	7	(7.1)	11	18.66	8	(8.1)	12	21.41
>=75 years	1	(5.3)	2	18.23	0			
Autonomic nervous system imbalance								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Burning sensation								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Carotid artery aneurysm								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Carpal tunnel syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Cerebral infarction								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Cervicobrachial syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Dizziness								
>=18 - <65 years	3	(2.1)	4	4.69	6	(4.0)	9	10.25
>=65 - <75 years	0				3	(3.0)	4	7.14
>=75 years	1	(5.3)	1	9.12	0			
Facial paralysis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Headache								
>=18 - <65 years	11	(7.6)	16	18.75	8	(5.4)	9	10.25
>=65 - <75 years	3	(3.0)	4	6.78	1	(1.0)	1	1.78
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoaesthesia								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Migraine								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Neuralgia								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Neuropathy peripheral								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Peripheral paralysis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Piriformis syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Post herpetic neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Restless legs syndrome								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Sciatica								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	2	(2.0)	2	3.57
>=75 years	0				0			
Somnolence								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Syncope								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tension headache								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thalamic infarction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombotic stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Tremor								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Psychiatric disorders								
All								
>=18 - <65 years	3	(2.1)	3	3.52	2	(1.3)	2	2.28
>=65 - <75 years	1	(1.0)	2	3.39	3	(3.0)	3	5.35
>=75 years	0				0			
Adjustment disorder								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depression								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Insomnia								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Major depression								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
>=18 - <65 years	5	(3.5)	7	8.21	0			
>=65 - <75 years	2	(2.0)	2	3.39	0			
>=75 years	1	(5.3)	1	9.12	0			
Bladder prolapse								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic nephropathy								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Hydronephrosis								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nephrotic syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Pollakiuria								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Polyuria								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal impairment								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Urethral stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Urine odour abnormal								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
>=18 - <65 years	3	(2.1)	3	3.52	1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	1	(1.0)	1	1.78
>=75 years	0				0			
Benign prostatic hyperplasia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Cervical polyp								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Erectile dysfunction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatitis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Pruritus genital								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	10	(6.9)	22	25.79	2	(1.3)	2	2.28
>=65 - <75 years	4	(4.0)	6	10.18	2	(2.0)	3	5.35
>=75 years	1	(5.3)	1	9.12	0			
Acute respiratory failure								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Chronic obstructive pulmonary disease								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Cough								
>=18 - <65 years	2	(1.4)	3	3.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epistaxis								
>=18 - <65 years	3	(2.1)	7	8.21	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasal congestion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Nasal obstruction								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasal septum deviation								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				1	(1.0)	2	3.57
>=75 years	0				0			
Productive cough								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Respiratory failure								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	3	(2.1)	5	5.86	0			
>=65 - <75 years	2	(2.0)	2	3.39	1	(1.0)	1	1.78
>=75 years	0				0			
Sleep apnoea syndrome								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Sneezing								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin and subcutaneous tissue disorders								
All								
>=18 - <65 years	7	(4.9)	8	9.38	4	(2.7)	4	4.56
>=65 - <75 years	5	(5.1)	5	8.48	1	(1.0)	1	1.78
>=75 years	1	(5.3)	1	9.12	1	(6.7)	1	11.18

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alopecia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(5.3)	1	9.12	0			
Blister								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Dermal cyst								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis								
>=18 - <65 years	0				1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperhidrosis								
>=18 - <65 years	1	(0.7)	1	1.17	1	(0.7)	1	1.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Miliaria								
>=18 - <65 years	1	(0.7)	1	1.17	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Neurodermatitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.7)	1	11.18
Pruritus								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Rash								
>=18 - <65 years	3	(2.1)	3	3.52	0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Rash papular								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	2	(1.4)	2	2.34	0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Toe amputation								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.78
>=75 years	0				0			
Vascular disorders								
All								
>=18 - <65 years	1	(0.7)	1	1.17	4	(2.7)	4	4.56
>=65 - <75 years	4	(4.0)	4	6.78	1	(1.0)	1	1.78
>=75 years	0				0			
Hypertension								
>=18 - <65 years	1	(0.7)	1	1.17	4	(2.7)	4	4.56
>=65 - <75 years	3	(3.0)	3	5.09	1	(1.0)	1	1.78
>=75 years	0				0			
Orthostatic hypotension								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.0)	1	1.70	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.15 Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	189				184			
>=65 - <75 years	92				96			
>=75 years	10				11			
PYE (years)								
>=18 - <65 years	108.79				105.57			
>=65 - <75 years	53.20				54.69			
>=75 years	5.37				6.54			
Events								
>=18 - <65 years	100	(52.9)	239	219.70	98	(53.3)	336	318.28
>=65 - <75 years	63	(68.5)	201	377.81	62	(64.6)	203	371.16
>=75 years	8	(80.0)	15	279.10	7	(63.6)	11	168.32
Blood and lymphatic system disorders								
All								
>=18 - <65 years	3	(1.6)	3	2.76	4	(2.2)	4	3.79
>=65 - <75 years	4	(4.3)	4	7.52	1	(1.0)	1	1.83
>=75 years	0				0			
Anaemia								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Blood loss anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Eosinophilia								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Iron deficiency anaemia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Lymphadenopathy mediastinal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Cardiac disorders								
All								
>=18 - <65 years	1	(0.5)	1	0.92	9	(4.9)	16	15.16
>=65 - <75 years	5	(5.4)	6	11.28	5	(5.2)	6	10.97
>=75 years	1	(10.0)	1	18.61	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute myocardial infarction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Angina pectoris								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	1	(10.0)	1	18.61	0			
Aortic valve calcification								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Aortic valve sclerosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Atrial enlargement								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Bundle branch block left								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Bundle branch block right								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Cardiac failure								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac failure congestive								
>=18 - <65 years	0				2	(1.1)	3	2.84
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac perfusion defect								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronary artery disease								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Left atrial enlargement								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Left ventricular hypertrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Myocardial infarction								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Myocardial ischaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Palpitations								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Pericarditis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Sinus bradycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Tachycardia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Congenital, familial and genetic disorders								
All								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Corneal dystrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	0				3	(1.6)	3	2.84
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	1	(10.0)	1	18.61	1	(9.1)	1	15.30
Cerumen impaction								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	1	(10.0)	1	18.61	0			
Ear discomfort								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Middle ear inflammation								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Vertigo								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				1	(9.1)	1	15.30
Endocrine disorders								
All								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Adrenocortical insufficiency acute								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypogonadism								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	13	(6.9)	17	15.63	21	(11.4)	25	23.68
>=65 - <75 years	12	(13.0)	14	26.31	17	(17.7)	32	58.51
>=75 years	1	(10.0)	2	37.21	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Age-related macular degeneration								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Astigmatism								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract								
>=18 - <65 years	1	(0.5)	1	0.92	4	(2.2)	6	5.68
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Corneal erosion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	7	(3.7)	8	7.35	7	(3.8)	7	6.63
>=65 - <75 years	4	(4.3)	5	9.40	8	(8.3)	8	14.63
>=75 years	1	(10.0)	1	18.61	0			
Diplopia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Eye discharge								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye inflammation								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Eye pain								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Macular degeneration								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				1	(1.0)	1	1.83

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	1	(10.0)	1	18.61	0			
Meibomianitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Open angle glaucoma								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Presbyopia								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal deposits								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Retinal detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Retinal drusen								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Retinal exudates								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Retinal haemorrhage								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Retinal scar								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vascular disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy hypertensive								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	0				1	(0.5)	1	0.95

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Visual impairment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	9	16.46
>=75 years	0				0			
Vitreous detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Vitreous haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Gastrointestinal disorders								
All								
>=18 - <65 years	20	(10.6)	29	26.66	23	(12.5)	32	30.31
>=65 - <75 years	13	(14.1)	19	35.71	12	(12.5)	17	31.08
>=75 years	2	(20.0)	2	37.21	0			
Abdominal discomfort								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				1	(1.0)	2	3.66
>=75 years	0				0			
Abdominal distension								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain								
>=18 - <65 years	0				5	(2.7)	6	5.68
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	1	(10.0)	1	18.61	0			
Abdominal pain upper								
>=18 - <65 years	1	(0.5)	1	0.92	2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Constipation								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Dental caries								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				2	(2.1)	2	3.66

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Diarrhoea								
>=18 - <65 years	8	(4.2)	10	9.19	7	(3.8)	7	6.63
>=65 - <75 years	6	(6.5)	7	13.16	2	(2.1)	2	3.66
>=75 years	1	(10.0)	1	18.61	0			
Eructation								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Faeces pale								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Food poisoning								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Gastrointestinal disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Gastrointestinal haemorrhage								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrooesophageal reflux disease								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Gingival disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Hypoaesthesia oral								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.2)	4	7.52	0			
>=75 years	0				0			
Nausea								
>=18 - <65 years	4	(2.1)	4	3.68	3	(1.6)	3	2.84
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Pancreatic duct dilatation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Pancreatic failure								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Pancreatitis chronic								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Periodontal disease								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Proctalgia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	3	5.49
>=75 years	0				0			
Upper gastrointestinal haemorrhage								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Vomiting								
>=18 - <65 years	7	(3.7)	9	8.27	1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	16	(8.5)	21	19.30	14	(7.6)	16	15.16
>=65 - <75 years	10	(10.9)	17	31.95	11	(11.5)	19	34.74
>=75 years	0				1	(9.1)	1	15.30
Asthenia								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				1	(9.1)	1	15.30
Axillary pain								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Chest pain								
>=18 - <65 years	3	(1.6)	3	2.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cyst								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Discomfort								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	8	14.63
>=75 years	0				0			
Facial pain								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Fatigue								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	2	(2.2)	3	5.64	0			
>=75 years	0				0			
Feeling abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Inflammation								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site pain								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Injection site rash								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site reaction								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	2	3.66
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Medical device site pain								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Multiple organ dysfunction syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Oedema due to renal disease								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oedema peripheral								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Pain								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	2	(2.2)	3	5.64	0			
>=75 years	0				0			
Peripheral swelling								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	2	(1.1)	2	1.84	4	(2.2)	5	4.74
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Thirst								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pruritus								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Xerosis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatobiliary disorders								
All								
>=18 - <65 years	0				2	(1.1)	4	3.79
>=65 - <75 years	2	(2.2)	3	5.64	2	(2.1)	2	3.66
>=75 years	0				0			
Biliary dyskinesia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cholecystitis chronic								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Gallbladder polyp								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic function abnormal								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic steatosis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatomegaly								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Hyperplastic cholecystopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Liver disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Drug hypersensitivity								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypersensitivity								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Infections and infestations								
All								
>=18 - <65 years	52	(27.5)	69	63.43	47	(25.5)	76	71.99
>=65 - <75 years	34	(37.0)	47	88.34	29	(30.2)	41	74.96
>=75 years	1	(10.0)	1	18.61	3	(27.3)	3	45.90
Abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Asymptomatic COVID-19								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Bacteraemia								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast abscess								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	5	(2.6)	5	4.60	1	(0.5)	1	0.95
>=65 - <75 years	3	(3.3)	3	5.64	2	(2.1)	2	3.66
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Candida infection								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cellulitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cholecystitis infective								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Coronavirus infection								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
COVID-19								
>=18 - <65 years	17	(9.0)	17	15.63	14	(7.6)	16	15.16
>=65 - <75 years	8	(8.7)	8	15.04	8	(8.3)	8	14.63
>=75 years	1	(10.0)	1	18.61	1	(9.1)	1	15.30
COVID-19 pneumonia								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Cystitis								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Diabetic foot infection								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Fungal infection								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fungal skin infection								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis								
>=18 - <65 years	5	(2.6)	5	4.60	4	(2.2)	4	3.79
>=65 - <75 years	2	(2.2)	2	3.76	1	(1.0)	2	3.66
>=75 years	0				0			
Gastroenteritis viral								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Gingivitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Herpes zoster								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Infected dermal cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Influenza								
>=18 - <65 years	4	(2.1)	4	3.68	6	(3.3)	8	7.58
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Laryngitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Localised infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Nasopharyngitis								
>=18 - <65 years	5	(2.6)	5	4.60	5	(2.7)	5	4.74
>=65 - <75 years	3	(3.3)	3	5.64	7	(7.3)	10	18.28
>=75 years	0				0			
Oral herpes								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	2	3.76	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Osteomyelitis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Otitis media								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media acute								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Paronychia								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Periodontitis								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Pharyngitis								
>=18 - <65 years	2	(1.1)	2	1.84	5	(2.7)	5	4.74
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Pharyngotonsillitis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumonia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	3	(3.3)	3	5.64	0			
>=75 years	0				0			
Pneumonia viral								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Post procedural infection								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary tuberculoma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulpitis dental								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Respiratory syncytial virus infection								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory tract infection								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Respiratory tract infection viral								
>=18 - <65 years	5	(2.6)	6	5.52	5	(2.7)	6	5.68
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Sepsis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	2	3.76	0			
>=75 years	0				0			
Soft tissue infection								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth abscess								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	3	5.49
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				1	(9.1)	1	15.30
Upper respiratory tract infection								
>=18 - <65 years	4	(2.1)	4	3.68	5	(2.7)	5	4.74
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				1	(9.1)	1	15.30
Urinary tract infection								
>=18 - <65 years	1	(0.5)	1	0.92	2	(1.1)	3	2.84
>=65 - <75 years	2	(2.2)	2	3.76	3	(3.1)	4	7.31
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Viral rhinitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral tracheitis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal mycotic infection								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injury, poisoning and procedural complications								
All								
>=18 - <65 years	10	(5.3)	14	12.87	14	(7.6)	18	17.05
>=65 - <75 years	9	(9.8)	11	20.68	13	(13.5)	17	31.08
>=75 years	0				0			
Accidental overdose								
>=18 - <65 years	0				1	(0.5)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Accidental underdose								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Animal bite								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod bite								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod sting								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chillblains								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Concussion								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Contusion								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Crush injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Exposure to SARS-CoV-2								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Extra dose administered								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fall								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Foot fracture								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Incorrect dose administered								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Joint injury								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ligament sprain								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Medication error								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Meniscus injury								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Muscle injury								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle strain								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Overdose								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Product administration error								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Skin laceration								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Spinal column injury								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Spinal compression fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Subcutaneous haematoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Subdural haematoma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Thermal burn								
>=18 - <65 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Tooth fracture								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Wound								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Wrong product administered								
>=18 - <65 years	1	(0.5)	2	1.84	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Investigations								
All								
>=18 - <65 years	7	(3.7)	9	8.27	6	(3.3)	7	6.63
>=65 - <75 years	4	(4.3)	5	9.40	7	(7.3)	7	12.80
>=75 years	1	(10.0)	1	18.61	0			
Amylase increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Blood alkaline phosphatase increased								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood creatinine increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Blood pressure increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Blood triglycerides increased								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood urine present								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83

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Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Catheterisation cardiac								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Electrocardiogram abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Electrocardiogram T wave inversion								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Eosinophil count increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Glomerular filtration rate decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Haematocrit increased								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoglobin increased								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Liver function test abnormal								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Liver function test increased								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	1	(10.0)	1	18.61	0			
Platelet count decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
SARS-CoV-2 test positive								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Transaminases increased								
>=18 - <65 years	0				1	(0.5)	1	0.95

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight increased								
>=18 - <65 years	5	(2.6)	5	4.60	3	(1.6)	3	2.84
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Metabolism and nutrition disorders								
All								
>=18 - <65 years	9	(4.8)	11	10.11	13	(7.1)	14	13.26
>=65 - <75 years	6	(6.5)	7	13.16	6	(6.3)	7	12.80
>=75 years	0				1	(9.1)	1	15.30
Decreased appetite								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Dehydration								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dyslipidaemia								
>=18 - <65 years	3	(1.6)	4	3.68	0			
>=65 - <75 years	0				3	(3.1)	3	5.49
>=75 years	0				0			
Fluid retention								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperglycaemia								
>=18 - <65 years	0				4	(2.2)	4	3.79
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Hyperkalaemia								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Hypertriglyceridaemia								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoalbuminaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Hypoglycaemia								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				1	(9.1)	1	15.30
Hypokalaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Hyponatraemia								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Increased appetite								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipomatosis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitamin D deficiency								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	16	(8.5)	19	17.47	23	(12.5)	34	32.21
>=65 - <75 years	13	(14.1)	19	35.71	10	(10.4)	12	21.94
>=75 years	3	(30.0)	3	55.82	2	(18.2)	2	30.60
Arthralgia								
>=18 - <65 years	3	(1.6)	4	3.68	6	(3.3)	6	5.68
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Arthritis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Back disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	3	(1.6)	3	2.76	5	(2.7)	5	4.74
>=65 - <75 years	4	(4.3)	4	7.52	4	(4.2)	4	7.31

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	1	(10.0)	1	18.61	2	(18.2)	2	30.60
Bone cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Bone pain								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Coccydynia								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Flank pain								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Foot deformity								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Intervertebral disc protrusion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Jaw disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Myalgia								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Myositis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Neck pain								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	3	(3.3)	3	5.64	0			
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	3	(1.6)	3	2.76	5	(2.7)	6	5.68

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD AGEGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	1	(10.0)	1	18.61	0			
Osteochondrosis								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Pain in extremity								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	2	3.66
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Periostitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Rotator cuff syndrome								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Spinal osteoarthritis								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Tendon disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Tendonitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Tenosynovitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Torticollis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	1	(10.0)	1	18.61	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	2	(1.1)	2	1.84	3	(1.6)	5	4.74
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Adrenal adenoma								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye naevus								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Lung adenocarcinoma								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteoma								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatic neoplasm								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Small cell lung cancer								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Small intestine neuroendocrine tumour								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Uterine cancer								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Uterine leiomyoma								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Nervous system disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	13	(6.9)	22	20.22	16	(8.7)	30	28.42
>=65 - <75 years	4	(4.3)	7	13.16	12	(12.5)	16	29.25
>=75 years	2	(20.0)	3	55.82	1	(9.1)	1	15.30
Anosmia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Basilar migraine								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Carpal tunnel syndrome								
>=18 - <65 years	1	(0.5)	1	0.92	2	(1.1)	2	1.89
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	1	(10.0)	1	18.61	0			
Cerebral arteriosclerosis								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebrovascular accident								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Cerebrovascular disorder								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cognitive disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				2	(2.1)	2	3.66
>=75 years	0				0			
Dizziness								
>=18 - <65 years	2	(1.1)	5	4.60	2	(1.1)	3	2.84
>=65 - <75 years	3	(3.3)	4	7.52	0			
>=75 years	0				0			
Dizziness postural								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(9.1)	1	15.30

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dysgeusia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Essential tremor								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Facial nerve disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Headache								
>=18 - <65 years	6	(3.2)	7	6.43	7	(3.8)	9	8.53
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	3	5.49
>=75 years	1	(10.0)	2	37.21	0			
Hemiparesis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoaesthesia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemic coma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Hyporeflexia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Memory impairment								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Migraine								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Morton's neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neuropathy peripheral								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Paraesthesia								
>=18 - <65 years	0				3	(1.6)	3	2.84
>=65 - <75 years	0				0			
>=75 years	0				0			
Sciatica								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Sleep deficit								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Transient ischaemic attack								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Tremor								
>=18 - <65 years	0				1	(0.5)	4	3.79
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	2	3.66
>=75 years	0				0			
Vascular encephalopathy								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
>=18 - <65 years	0				8	(4.3)	8	7.58
>=65 - <75 years	2	(2.2)	2	3.76	1	(1.0)	1	1.83
>=75 years	0				0			
Affect lability								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Depression								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Fear								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Insomnia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Mental status changes								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Mixed anxiety and depressive disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Phobia								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
>=18 - <65 years	0				4	(2.2)	4	3.79
>=65 - <75 years	4	(4.3)	7	13.16	2	(2.1)	2	3.66
>=75 years	0				0			
Acute kidney injury								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Chronic kidney disease								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(2.2)	2	3.76	1	(1.0)	1	1.83
>=75 years	0				0			
Dysuria								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Haematuria								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	2	3.76	0			
>=75 years	0				0			
Hydrocalyx								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Nephropathy								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal colic								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Benign prostatic hyperplasia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Menopausal disorder								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	9	(4.8)	10	9.19	9	(4.9)	12	11.37
>=65 - <75 years	8	(8.7)	10	18.80	10	(10.4)	11	20.11
>=75 years	0				0			
Asthma								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Bronchitis chronic								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cough								
>=18 - <65 years	2	(1.1)	2	1.84	2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Dyspnoea								
>=18 - <65 years	0				3	(1.6)	4	3.79
>=65 - <75 years	1	(1.1)	1	1.88	2	(2.1)	2	3.66
>=75 years	0				0			
Emphysema								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Epistaxis								
>=18 - <65 years	2	(1.1)	2	1.84	0			
>=65 - <75 years	0				1	(1.0)	2	3.66
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal congestion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Nasal septum deviation								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Paranasal cyst								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Pleurisy								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary fibrosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Pulmonary hypertension								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Respiratory disorder								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	1	(1.0)	1	1.83
>=75 years	0				0			
Rhinitis allergic								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Sinus congestion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus pain								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin and subcutaneous tissue disorders								
All								
>=18 - <65 years	4	(2.1)	4	3.68	12	(6.5)	13	12.31
>=65 - <75 years	8	(8.7)	9	16.92	1	(1.0)	1	1.83
>=75 years	0				2	(18.2)	2	30.60
Alopecia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Blister								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Cold sweat								
>=18 - <65 years	2	(1.1)	2	1.84	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis contact								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Eczema								
>=18 - <65 years	1	(0.5)	1	0.92	2	(1.1)	2	1.89
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperhidrosis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Hyperkeratosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(9.1)	1	15.30
Intertrigo								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Lipohypertrophy								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pruritus								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				1	(9.1)	1	15.30
Rash								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Seborrhoea								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin reaction								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin ulcer								
>=18 - <65 years	0				2	(1.1)	2	1.89
>=65 - <75 years	2	(2.2)	2	3.76	0			
>=75 years	0				0			
Umbilical haematoma								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Surgical and medical procedures								
All								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Cardiac pacemaker replacement								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Shoulder operation								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth extraction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
>=18 - <65 years	3	(1.6)	3	2.76	9	(4.9)	11	10.42
>=65 - <75 years	4	(4.3)	8	15.04	7	(7.3)	8	14.63
>=75 years	1	(10.0)	1	18.61	0			
Aortic arteriosclerosis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Arteriosclerosis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood pressure fluctuation								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Deep vein thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(10.0)	1	18.61	0			
Diabetic vascular disorder								
>=18 - <65 years	1	(0.5)	1	0.92	0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Haematoma								
>=18 - <65 years	1	(0.5)	1	0.92	1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertension								
>=18 - <65 years	1	(0.5)	1	0.92	2	(1.1)	2	1.89
>=65 - <75 years	1	(1.1)	1	1.88	4	(4.2)	4	7.31
>=75 years	0				0			
Hypertensive crisis								
>=18 - <65 years	0				1	(0.5)	3	2.84
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Hypertensive urgency								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypotension								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(1.0)	1	1.83
>=75 years	0				0			
Neovascularisation								
>=18 - <65 years	0				1	(0.5)	1	0.95

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by age group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Orthostatic hypotension								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Peripheral arterial occlusive disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Peripheral artery stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	3	5.64	0			
>=75 years	0				0			
Peripheral venous disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(1.1)	1	1.88	0			
>=75 years	0				0			
Thrombophlebitis								
>=18 - <65 years	0				1	(0.5)	1	0.95
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.16 Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main- on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	267				271			
>=65 - <75 years	20				18			
>=75 years	3				3			
PYE (years)								
>=18 - <65 years	131.27				133.59			
>=65 - <75 years	9.58				9.02			
>=75 years	1.46				1.52			
Events								
>=18 - <65 years	172	(64.4)	453	345.10	173	(63.8)	582	435.68
>=65 - <75 years	14	(70.0)	45	469.74	14	(77.8)	30	332.65
>=75 years	3	(100.0)	9	615.59	3	(100.0)	7	461.51
Blood and lymphatic system disorders								
All								
>=18 - <65 years	1	(0.4)	1	0.76	3	(1.1)	3	2.25
>=65 - <75 years	2	(10.0)	2	20.88	0			
>=75 years	0				0			
Anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Iron deficiency anaemia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphadenitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphadenopathy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Thrombocytopenia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	6	(2.2)	6	4.57	4	(1.5)	5	3.74
>=65 - <75 years	3	(15.0)	3	31.32	0			
>=75 years	0				1	(33.3)	1	65.93
Angina pectoris								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Angina unstable								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Bundle branch block right								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac failure								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiomegaly								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Cardiovascular disorder								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Myocardial ischaemia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Palpitations								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	65.93
Ventricular extrasystoles								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	2	(0.7)	2	1.52	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Deafness neurosensory								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ear pain								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Vertigo								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Endocrine disorders								
All								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	26	(9.7)	33	25.14	24	(8.9)	30	22.46
>=65 - <75 years	2	(10.0)	3	31.32	4	(22.2)	7	77.62
>=75 years	1	(33.3)	1	68.40	0			
Arteriosclerotic retinopathy								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Astigmatism								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
>=18 - <65 years	4	(1.5)	4	3.05	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract nuclear								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival haemorrhage								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Corneal erosion								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	10	(3.7)	10	7.62	14	(5.2)	14	10.48
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	1	(33.3)	1	68.40	0			
Dry eye								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Epiretinal membrane								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Glaucoma								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				3	(16.7)	3	33.27
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	3	(1.1)	4	3.05	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Myopia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-proliferative retinopathy								
>=18 - <65 years	1	(0.4)	1	0.76	2	(0.7)	2	1.50
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Ocular hypertension								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	2	22.18
>=75 years	0				0			
Photopsia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Posterior capsule opacification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Presbyopia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Pterygium								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vascular disorder								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy hypertensive								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitreous detachment								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vitreous floaters								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Gastrointestinal disorders								
All								
>=18 - <65 years	22	(8.2)	31	23.62	23	(8.5)	40	29.94
>=65 - <75 years	4	(20.0)	7	73.07	1	(5.6)	1	11.09
>=75 years	0				0			
Abdominal discomfort								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal distension								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain upper								
>=18 - <65 years	3	(1.1)	3	2.29	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Anal fissure								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Constipation								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dental caries								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diarrhoea								
>=18 - <65 years	5	(1.9)	6	4.57	4	(1.5)	5	3.74
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Diverticulum intestinal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Dyspepsia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Faeces soft								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric polyps								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastritis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Gastritis erosive								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrooesophageal reflux disease								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Gingival recession								
>=18 - <65 years	0				1	(0.4)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhoids								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hiatus hernia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Impaired gastric emptying								
>=18 - <65 years	1	(0.4)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Irritable bowel syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Lumbar hernia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Nausea								
>=18 - <65 years	4	(1.5)	4	3.05	8	(3.0)	8	5.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Odynophagia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatic failure								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumatosis intestinalis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	1	(0.4)	1	0.76	3	(1.1)	5	3.74
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Vomiting								
>=18 - <65 years	6	(2.2)	6	4.57	5	(1.8)	5	3.74
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	35	(13.1)	43	32.76	31	(11.4)	79	59.14
>=65 - <75 years	5	(25.0)	6	62.63	3	(16.7)	4	44.35
>=75 years	1	(33.3)	1	68.40	0			
Asthenia								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Chest pain								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Fatigue								
>=18 - <65 years	3	(1.1)	3	2.29	1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	2	20.88	0			
>=75 years	1	(33.3)	1	68.40	0			
Hunger								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperthermia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Inflammation								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Influenza like illness								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Injection site mass								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site pain								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site urticaria								
>=18 - <65 years	1	(0.4)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	3	(1.1)	3	2.29	3	(1.1)	44	32.94
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site bruise								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	2	(0.7)	2	1.52	2	(0.7)	2	1.50
>=65 - <75 years	1	(5.0)	1	10.44	1	(5.6)	2	22.18
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site erythema								
>=18 - <65 years	0				3	(1.1)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site haematoma								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Medical device site irritation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Medical device site pain								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pruritus								
>=18 - <65 years	1	(0.4)	1	0.76	3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site rash								
>=18 - <65 years	5	(1.9)	5	3.81	7	(2.6)	7	5.24
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oedema peripheral								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Pain								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	9	(3.4)	10	7.62	5	(1.8)	5	3.74
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Swelling face								
>=18 - <65 years	1	(0.4)	1	0.76	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatobiliary disorders								
All								
>=18 - <65 years	4	(1.5)	5	3.81	3	(1.1)	3	2.25
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				1	(33.3)	1	65.93
Gallbladder disorder								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Gallbladder polyp								
>=18 - <65 years	1	(0.4)	1	0.76	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic calcification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Hepatic steatosis								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	65.93
Hypertransaminasaemia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypersensitivity								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Infections and infestations								
All								
>=18 - <65 years	100	(37.5)	139	105.89	94	(34.7)	137	102.56
>=65 - <75 years	4	(20.0)	8	83.51	5	(27.8)	7	77.62
>=75 years	0				2	(66.7)	4	263.72
Abscess limb								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute sinusitis								
>=18 - <65 years	0				3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast abscess								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	3	(1.1)	3	2.29	1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	1	(5.6)	1	11.09
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	4	(1.5)	4	3.05	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Coronavirus infection								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

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Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19								
>=18 - <65 years	26	(9.7)	27	20.57	32	(11.8)	34	25.45
>=65 - <75 years	3	(15.0)	3	31.32	0			
>=75 years	0				0			
COVID-19 pneumonia								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cystitis								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Cystitis escherichia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye infection								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal skin infection								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric infection								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis								
>=18 - <65 years	6	(2.2)	7	5.33	1	(0.4)	1	0.75
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Gastroenteritis viral								
>=18 - <65 years	1	(0.4)	1	0.76	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrointestinal infection								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	2	131.86
Genital infection fungal								
>=18 - <65 years	1	(0.4)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gingivitis								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes zoster								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Hordeolum								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Infected cyst								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Influenza								
>=18 - <65 years	1	(0.4)	1	0.76	5	(1.8)	5	3.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngitis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Localised infection								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Lower respiratory tract infection								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasopharyngitis								
>=18 - <65 years	33	(12.4)	41	31.23	33	(12.2)	38	28.45
>=65 - <75 years	1	(5.0)	1	10.44	2	(11.1)	4	44.35
>=75 years	0				1	(33.3)	1	65.93
Norovirus infection								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis externa								
>=18 - <65 years	0				3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis media								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontitis								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Pharyngitis								
>=18 - <65 years	5	(1.9)	5	3.81	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumonia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory tract infection								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory tract infection viral								
>=18 - <65 years	3	(1.1)	3	2.29	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinitis								
>=18 - <65 years	1	(0.4)	1	0.76	4	(1.5)	5	3.74
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Severe acute respiratory syndrome								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	5	(1.9)	5	3.81	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin infection								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinea cruris								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tinea pedis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	65.93
Tonsillitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth abscess								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper respiratory tract infection								
>=18 - <65 years	5	(1.9)	5	3.81	7	(2.6)	8	5.99
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Urinary tract infection								
>=18 - <65 years	6	(2.2)	6	4.57	6	(2.2)	8	5.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaginal infection								
>=18 - <65 years	1	(0.4)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral infection								
>=18 - <65 years	1	(0.4)	1	0.76	4	(1.5)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injury, poisoning and procedural complications								
All								
>=18 - <65 years	27	(10.1)	34	25.90	30	(11.1)	36	26.95

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	3	(15.0)	3	31.32	3	(16.7)	3	33.27
>=75 years	0				0			
Accidental overdose								
>=18 - <65 years	6	(2.2)	7	5.33	1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Anaemia postoperative								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Animal scratch								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod bite								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Back injury								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Burns first degree								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Clavicle fracture								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Contusion								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	1	(5.6)	1	11.09
>=75 years	0				0			
Corneal abrasion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Epicondylitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Face injury								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fall								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibula fracture								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hand fracture								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Heat stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Incorrect dose administered								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint injury								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Ligament sprain								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medication error								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle strain								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Nerve injury								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Prescribed overdose								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	5	(1.9)	5	3.81	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Procedural pain								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Product administration error								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Product dispensing error								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Radius fracture								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Road traffic accident								
>=18 - <65 years	1	(0.4)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	1	(0.4)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin laceration								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth fracture								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	4	(1.5)	4	3.05	8	(3.0)	11	8.23
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Wound								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Wound dehiscence								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Wrong product administered								
>=18 - <65 years	0				4	(1.5)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Investigations								
All								
>=18 - <65 years	12	(4.5)	12	9.14	12	(4.4)	14	10.48
>=65 - <75 years	2	(10.0)	3	31.32	1	(5.6)	1	11.09
>=75 years	0				0			
Angiogram								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Aspartate aminotransferase increased								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood cholesterol increased								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Blood glucose increased								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood pressure increased								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood testosterone decreased								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood triglycerides increased								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood uric acid increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Cardiac murmur								
>=18 - <65 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram abnormal								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Eosinophil count increased								
>=18 - <65 years	0				1	(0.4)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoglobin decreased								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Heart rate increased								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic enzyme increased								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatitis B virus test positive								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipids abnormal								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Low density lipoprotein increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Mycobacterium tuberculosis complex test positive								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Occult blood positive								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
SARS-CoV-2 test positive								
>=18 - <65 years	0				4	(1.5)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Weight decreased								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight increased								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
White blood cell count decreased								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
>=18 - <65 years	8	(3.0)	10	7.62	9	(3.3)	11	8.23
>=65 - <75 years	0				0			
>=75 years	0				0			
Dehydration								
>=18 - <65 years	0				1	(0.4)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperuricaemia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemia								
>=18 - <65 years	5	(1.9)	7	5.33	3	(1.1)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyponatraemia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Insulin resistance								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Obesity								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitamin D deficiency								
>=18 - <65 years	1	(0.4)	1	0.76	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	24	(9.0)	27	20.57	37	(13.7)	61	45.66
>=65 - <75 years	2	(10.0)	3	31.32	2	(11.1)	2	22.18
>=75 years	1	(33.3)	1	68.40	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthralgia								
>=18 - <65 years	4	(1.5)	4	3.05	9	(3.3)	9	6.74
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	1	(33.3)	1	68.40	0			
Arthritis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	2	(0.7)	2	1.52	10	(3.7)	24	17.97
>=65 - <75 years	1	(5.0)	1	10.44	1	(5.6)	1	11.09
>=75 years	0				0			
Bursitis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Chondromalacia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Groin pain								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb discomfort								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb mass								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscular weakness								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal stiffness								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myalgia								
>=18 - <65 years	2	(0.7)	2	1.52	7	(2.6)	8	5.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Neck pain								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nodal osteoarthritis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	3	(1.1)	3	2.29	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Pain in extremity								
>=18 - <65 years	5	(1.9)	5	3.81	6	(2.2)	6	4.49
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	0				3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Rheumatoid arthritis								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Synovial cyst								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tendonitis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Tenosynovitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	4	(1.5)	4	3.05	2	(0.7)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign neoplasm of thyroid gland								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign renal neoplasm								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye naevus								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemangioma of liver								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Melanocytic naevus								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Uterine leiomyoma								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Nervous system disorders								
All								
>=18 - <65 years	23	(8.6)	42	32.00	20	(7.4)	74	55.40
>=65 - <75 years	2	(10.0)	2	20.88	3	(16.7)	3	33.27
>=75 years	2	(66.7)	2	136.80	1	(33.3)	1	65.93
Autonomic nervous system imbalance								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Burning sensation								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Carpal tunnel syndrome								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervicobrachial syndrome								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Disturbance in attention								
>=18 - <65 years	1	(0.4)	9	6.86	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dizziness								
>=18 - <65 years	1	(0.4)	2	1.52	1	(0.4)	2	1.50
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				1	(33.3)	1	65.93
Dizziness postural								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Encephalopathy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhage intracranial								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Headache								
>=18 - <65 years	12	(4.5)	18	13.71	9	(3.3)	12	8.98
>=65 - <75 years	1	(5.0)	1	10.44	1	(5.6)	1	11.09
>=75 years	0				0			
Hypoaesthesia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemic seizure								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemic unconsciousness								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypotonia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Loss of consciousness								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Migraine								
>=18 - <65 years	2	(0.7)	3	2.29	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Neuropathy peripheral								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Post herpetic neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Sinus headache								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Somnolence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Speech disorder								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Syncope								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tremor								
>=18 - <65 years	1	(0.4)	1	0.76	2	(0.7)	49	36.68
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
>=18 - <65 years	5	(1.9)	5	3.81	6	(2.2)	7	5.24
>=65 - <75 years	0				0			
>=75 years	0				0			
Anxiety								
>=18 - <65 years	1	(0.4)	1	0.76	4	(1.5)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Attention deficit hyperactivity disorder								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depressed mood								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depression								
>=18 - <65 years	0				3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Insomnia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
>=18 - <65 years	3	(1.1)	3	2.29	3	(1.1)	6	4.49
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic kidney disease								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic nephropathy								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Hydrocalyx								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertensive nephropathy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Microalbuminuria								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal pain								
>=18 - <65 years	2	(0.7)	2	1.52	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
>=18 - <65 years	3	(1.1)	3	2.29	4	(1.5)	6	4.49
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Benign prostatic hyperplasia								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dysmenorrhoea								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Ectropion of cervix								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibrocystic breast disease								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian disorder								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Penile pain								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Premenstrual syndrome								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatomegaly								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	19	(7.1)	22	16.76	21	(7.7)	29	21.71
>=65 - <75 years	1	(5.0)	2	20.88	0			
>=75 years	1	(33.3)	2	136.80	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Allergic cough								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchial hyperreactivity								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cough								
>=18 - <65 years	2	(0.7)	3	2.29	8	(3.0)	9	6.74
>=65 - <75 years	1	(5.0)	2	20.88	0			
>=75 years	0				0			
Dyspnoea exertional								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Epistaxis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hiccups								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Nasal congestion								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	5	(1.9)	5	3.81	3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Pleurisy								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Productive cough								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary congestion								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory disorder								
>=18 - <65 years	4	(1.5)	4	3.05	2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinitis allergic								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	2	(0.7)	2	1.52	6	(2.2)	6	4.49
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinus congestion								
>=18 - <65 years	2	(0.7)	2	1.52	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Sneezing								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Throat irritation								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper-airway cough syndrome								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin and subcutaneous tissue disorders								
All								
>=18 - <65 years	22	(8.2)	22	16.76	22	(8.1)	30	22.46
>=65 - <75 years	1	(5.0)	1	10.44	2	(11.1)	2	22.18
>=75 years	1	(33.3)	1	68.40	0			
Alopecia								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Angioedema								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Blister								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Chronic spontaneous urticaria								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Cold sweat								
>=18 - <65 years	0				4	(1.5)	8	5.99
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Dermal cyst								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis								
>=18 - <65 years	4	(1.5)	4	3.05	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis atopic								
>=18 - <65 years	0				2	(0.7)	2	1.50
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis contact								
>=18 - <65 years	2	(0.7)	2	1.52	5	(1.8)	5	3.74
>=65 - <75 years	0				1	(5.6)	1	11.09
>=75 years	0				0			
Dry skin								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Erythema								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Hidradenitis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperkeratosis								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ingrown hair								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lichen sclerosus								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Macule								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pruritus								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Rash								
>=18 - <65 years	3	(1.1)	3	2.29	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Rash erythematous								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin irritation								
>=18 - <65 years	1	(0.4)	1	0.76	1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	68.40	0			
Skin lesion								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Telangiectasia								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	0				3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Xeroderma								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by age group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Cardiac ablation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	10.44	0			
>=75 years	0				0			
Skin neoplasm excision								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vascular disorders								
All								
>=18 - <65 years	6	(2.2)	6	4.57	4	(1.5)	4	2.99
>=65 - <75 years	0				0			
>=75 years	0				0			
Arteriosclerosis								
>=18 - <65 years	1	(0.4)	1	0.76	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertension								
>=18 - <65 years	5	(1.9)	5	3.81	3	(1.1)	3	2.25
>=65 - <75 years	0				0			
>=75 years	0				0			
Varicose vein								
>=18 - <65 years	0				1	(0.4)	1	0.75
>=65 - <75 years	0				0			
>=75 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.17 Adverse events by baseline HbA1c group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	170				188			
>=8% (>=64 mmol/mol)	322				304			
PYE (years)								
<8% (<64 mmol/mol)	167.84				186.31			
>=8% (>=64 mmol/mol)	318.04				298.73			
Events								
<8% (<64 mmol/mol)	120	(70.6)	453	269.90	131	(69.7)	496	266.23
>=8% (>=64 mmol/mol)	231	(71.7)	774	243.37	204	(67.1)	666	222.94
Serious								
Yes								
<8% (<64 mmol/mol)	17	(10.0)	25	14.90	19	(10.1)	25	13.42
>=8% (>=64 mmol/mol)	34	(10.6)	49	15.41	30	(9.9)	48	16.07
No								
<8% (<64 mmol/mol)	118	(69.4)	428	255.00	129	(68.6)	471	252.81
>=8% (>=64 mmol/mol)	220	(68.3)	725	227.96	199	(65.5)	618	206.88
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	5	(2.9)	7	4.17	5	(2.7)	9	4.83
>=8% (>=64 mmol/mol)	13	(4.0)	19	5.97	15	(4.9)	25	8.37
Moderate								
<8% (<64 mmol/mol)	46	(27.1)	101	60.18	52	(27.7)	109	58.51
>=8% (>=64 mmol/mol)	106	(32.9)	179	56.28	84	(27.6)	142	47.53
Mild								
<8% (<64 mmol/mol)	108	(63.5)	345	205.55	117	(62.2)	378	202.89
>=8% (>=64 mmol/mol)	184	(57.1)	576	181.11	169	(55.6)	499	167.04
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): OTMTDURY HBAGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & ANELFL == "Y" & ANL06FL == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:11:05 - taesumgrptrl/taegrphba1csumontow1sas.txt

Adverse events by baseline HbA1c group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	5	(2.9)	11	6.55	10	(5.3)	13	6.98
>=8% (>=64 mmol/mol)	14	(4.3)	16	5.03	19	(6.3)	32	10.71
Possible								
<8% (<64 mmol/mol)	16	(9.4)	20	11.92	12	(6.4)	24	12.88
>=8% (>=64 mmol/mol)	18	(5.6)	26	8.18	19	(6.3)	22	7.36
Unlikely								
<8% (<64 mmol/mol)	118	(69.4)	421	250.83	128	(68.1)	458	245.83
>=8% (>=64 mmol/mol)	225	(69.9)	732	230.16	197	(64.8)	612	204.87
Missing								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
No								
<8% (<64 mmol/mol)	119	(70.0)	452	269.30	131	(69.7)	495	265.69
>=8% (>=64 mmol/mol)	231	(71.7)	774	243.37	204	(67.1)	666	222.94
NA								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	3	(0.9)	4	1.26	2	(0.7)	3	1.00
Not recovered/not resolved								
<8% (<64 mmol/mol)	54	(31.8)	120	71.50	59	(31.4)	118	63.34
>=8% (>=64 mmol/mol)	103	(32.0)	204	64.14	100	(32.9)	172	57.58
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	4	(2.4)	4	2.38	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	3	(1.0)	4	1.34
Recovering/resolving								
<8% (<64 mmol/mol)	8	(4.7)	14	8.34	7	(3.7)	7	3.76
>=8% (>=64 mmol/mol)	11	(3.4)	12	3.77	13	(4.3)	14	4.69
Recovered/resolved								
<8% (<64 mmol/mol)	107	(62.9)	314	187.08	121	(64.4)	369	198.06
>=8% (>=64 mmol/mol)	201	(62.4)	552	173.56	172	(56.6)	473	158.34
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.18 Adverse events by baseline HbA1c group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	126				125			
>=8% (>=64 mmol/mol)	136				138			
PYE (years)								
<8% (<64 mmol/mol)	75.04				72.76			
>=8% (>=64 mmol/mol)	80.20				80.01			
Events								
<8% (<64 mmol/mol)	76	(60.3)	233	310.48	55	(44.0)	116	159.43
>=8% (>=64 mmol/mol)	85	(62.5)	233	290.51	79	(57.2)	212	264.96
Serious								
Yes								
<8% (<64 mmol/mol)	6	(4.8)	8	10.66	5	(4.0)	8	10.99
>=8% (>=64 mmol/mol)	16	(11.8)	22	27.43	11	(8.0)	12	15.00
No								
<8% (<64 mmol/mol)	76	(60.3)	225	299.82	54	(43.2)	108	148.43
>=8% (>=64 mmol/mol)	82	(60.3)	211	263.08	74	(53.6)	200	249.97
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	1	(0.8)	2	2.67	3	(2.4)	3	4.12
>=8% (>=64 mmol/mol)	10	(7.4)	15	18.70	8	(5.8)	10	12.50
Moderate								
<8% (<64 mmol/mol)	30	(23.8)	49	65.29	22	(17.6)	34	46.73
>=8% (>=64 mmol/mol)	34	(25.0)	73	91.02	32	(23.2)	48	59.99
Mild								
<8% (<64 mmol/mol)	66	(52.4)	182	242.52	45	(36.0)	79	108.57
>=8% (>=64 mmol/mol)	66	(48.5)	145	180.79	64	(46.4)	154	192.47
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	6	(4.8)	6	8.00	5	(4.0)	8	10.99
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	1	(0.7)	5	6.25
Possible								
<8% (<64 mmol/mol)	10	(7.9)	18	23.99	3	(2.4)	3	4.12
>=8% (>=64 mmol/mol)	6	(4.4)	8	9.97	4	(2.9)	4	5.00
Unlikely								
<8% (<64 mmol/mol)	73	(57.9)	204	271.84	53	(42.4)	104	142.93
>=8% (>=64 mmol/mol)	82	(60.3)	217	270.56	77	(55.8)	201	251.22
Missing								
<8% (<64 mmol/mol)	3	(2.4)	5	6.66	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	3	(2.2)	5	6.23	2	(1.4)	2	2.50
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
No								
<8% (<64 mmol/mol)	76	(60.3)	228	303.82	53	(42.4)	114	156.68
>=8% (>=64 mmol/mol)	84	(61.8)	226	281.79	78	(56.5)	209	261.21
NA								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Missing								
<8% (<64 mmol/mol)	3	(2.4)	5	6.66	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	3	(2.2)	5	6.23	2	(1.4)	2	2.50

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	1	(0.8)	2	2.67	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	2	(1.4)	2	2.50
Not recovered/not resolved								
<8% (<64 mmol/mol)	23	(18.3)	34	45.31	20	(16.0)	27	37.11
>=8% (>=64 mmol/mol)	32	(23.5)	63	78.55	28	(20.3)	36	44.99
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Recovering/resolving								
<8% (<64 mmol/mol)	9	(7.1)	13	17.32	4	(3.2)	4	5.50
>=8% (>=64 mmol/mol)	10	(7.4)	11	13.72	12	(8.7)	13	16.25
Recovered/resolved								
<8% (<64 mmol/mol)	69	(54.8)	184	245.19	43	(34.4)	85	116.82
>=8% (>=64 mmol/mol)	66	(48.5)	158	197.00	57	(41.3)	160	199.97
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.19 Adverse events by baseline HbA1c group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	117				120			
>=8% (>=64 mmol/mol)	174				171			
PYE (years)								
<8% (<64 mmol/mol)	68.43				68.87			
>=8% (>=64 mmol/mol)	98.93				97.92			
Events								
<8% (<64 mmol/mol)	76	(65.0)	196	286.41	73	(60.8)	277	402.19
>=8% (>=64 mmol/mol)	95	(54.6)	259	261.80	94	(55.0)	273	278.79
Serious								
Yes								
<8% (<64 mmol/mol)	10	(8.5)	14	20.46	11	(9.2)	13	18.88
>=8% (>=64 mmol/mol)	12	(6.9)	21	21.23	14	(8.2)	20	20.42
No								
<8% (<64 mmol/mol)	74	(63.2)	182	265.96	69	(57.5)	264	383.31
>=8% (>=64 mmol/mol)	90	(51.7)	238	240.58	91	(53.2)	253	258.36
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	6	(5.1)	8	11.69	6	(5.0)	8	11.62
>=8% (>=64 mmol/mol)	7	(4.0)	12	12.13	6	(3.5)	6	6.13
Moderate								
<8% (<64 mmol/mol)	31	(26.5)	57	83.29	20	(16.7)	42	60.98
>=8% (>=64 mmol/mol)	28	(16.1)	42	42.45	41	(24.0)	79	80.67
Mild								
<8% (<64 mmol/mol)	59	(50.4)	131	191.43	67	(55.8)	227	329.59
>=8% (>=64 mmol/mol)	79	(45.4)	205	207.22	81	(47.4)	188	191.98
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	2	(1.7)	5	7.31	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	7	(4.0)	8	8.09	5	(2.9)	6	6.13
Possible								
<8% (<64 mmol/mol)	11	(9.4)	19	27.76	10	(8.3)	30	43.56
>=8% (>=64 mmol/mol)	12	(6.9)	15	15.16	7	(4.1)	13	13.28
Unlikely								
<8% (<64 mmol/mol)	68	(58.1)	172	251.34	71	(59.2)	245	355.73
>=8% (>=64 mmol/mol)	89	(51.1)	236	238.55	91	(53.2)	254	259.38
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	2	2.04
No								
<8% (<64 mmol/mol)	75	(64.1)	192	280.57	73	(60.8)	275	399.28
>=8% (>=64 mmol/mol)	95	(54.6)	258	260.79	94	(55.0)	270	275.72
NA								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.1)	4	4.04	1	(0.6)	1	1.02
Not recovered/not resolved								
<8% (<64 mmol/mol)	36	(30.8)	58	84.75	32	(26.7)	76	110.35
>=8% (>=64 mmol/mol)	42	(24.1)	81	81.88	41	(24.0)	76	77.61
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Recovering/resolving								
<8% (<64 mmol/mol)	6	(5.1)	6	8.77	8	(6.7)	10	14.52
>=8% (>=64 mmol/mol)	10	(5.7)	26	26.28	8	(4.7)	12	12.25
Recovered/resolved								
<8% (<64 mmol/mol)	64	(54.7)	132	192.89	62	(51.7)	190	275.87
>=8% (>=64 mmol/mol)	79	(45.4)	148	149.60	80	(46.8)	183	186.88
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): OTMTDURY HBAGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & ANELFL == "Y" & ANL06FL == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:11:08 - taesumgrptrl/taegrphba1csumontow4sas.txt

7.16.20 Adverse events by baseline HbA1c group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	189				189			
>=8% (>=64 mmol/mol)	101				103			
PYE (years)								
<8% (<64 mmol/mol)	92.25				93.57			
>=8% (>=64 mmol/mol)	50.06				50.55			
Events								
<8% (<64 mmol/mol)	121	(64.0)	312	338.22	124	(65.6)	363	387.93
>=8% (>=64 mmol/mol)	68	(67.3)	195	389.52	66	(64.1)	256	506.47
Serious								
Yes								
<8% (<64 mmol/mol)	5	(2.6)	5	5.42	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	6	(5.9)	10	19.98	3	(2.9)	5	9.89
No								
<8% (<64 mmol/mol)	119	(63.0)	307	332.80	121	(64.0)	359	383.65
>=8% (>=64 mmol/mol)	66	(65.3)	185	369.54	66	(64.1)	251	496.58
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	5	(2.6)	5	5.42	3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	4	(4.0)	5	9.99	1	(1.0)	2	3.96
Moderate								
<8% (<64 mmol/mol)	31	(16.4)	62	67.21	33	(17.5)	63	67.33
>=8% (>=64 mmol/mol)	20	(19.8)	28	55.93	18	(17.5)	26	51.44
Mild								
<8% (<64 mmol/mol)	107	(56.6)	245	265.59	109	(57.7)	297	317.39
>=8% (>=64 mmol/mol)	62	(61.4)	162	323.60	61	(59.2)	228	451.07
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	9	(4.8)	9	9.76	5	(2.6)	6	6.41
>=8% (>=64 mmol/mol)	8	(7.9)	11	21.97	2	(1.9)	2	3.96
Possible								
<8% (<64 mmol/mol)	10	(5.3)	12	13.01	10	(5.3)	28	29.92
>=8% (>=64 mmol/mol)	12	(11.9)	14	27.97	7	(6.8)	13	25.72
Unlikely								
<8% (<64 mmol/mol)	117	(61.9)	291	315.46	124	(65.6)	329	351.59
>=8% (>=64 mmol/mol)	61	(60.4)	170	339.58	65	(63.1)	241	476.79
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
No								
<8% (<64 mmol/mol)	121	(64.0)	312	338.22	124	(65.6)	363	387.93
>=8% (>=64 mmol/mol)	68	(67.3)	195	389.52	66	(64.1)	256	506.47
NA								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Not recovered/not resolved								
<8% (<64 mmol/mol)	57	(30.2)	83	89.98	53	(28.0)	98	104.73
>=8% (>=64 mmol/mol)	29	(28.7)	51	101.87	30	(29.1)	46	91.01
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Recovering/resolving								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	3	(2.9)	6	11.87
Recovered/resolved								
<8% (<64 mmol/mol)	104	(55.0)	225	243.91	106	(56.1)	261	278.92
>=8% (>=64 mmol/mol)	56	(55.4)	141	281.65	55	(53.4)	203	401.61
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.21 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	170				188			
>=8% (>=64 mmol/mol)	322				304			
PYE (years)								
<8% (<64 mmol/mol)	167.84				186.31			
>=8% (>=64 mmol/mol)	318.04				298.73			
Events								
<8% (<64 mmol/mol)	120	(70.6)	453	269.90	131	(69.7)	496	266.23
>=8% (>=64 mmol/mol)	231	(71.7)	774	243.37	204	(67.1)	666	222.94
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	5	(2.7)	5	2.68
>=8% (>=64 mmol/mol)	8	(2.5)	8	2.52	6	(2.0)	6	2.01
Anaemia								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	3	(1.0)	3	1.00
Blood loss anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Eosinophilia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Hypochromic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Iron deficiency anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Lymphadenopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Polycythaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Thrombocytopenia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	15	(8.8)	25	14.90	12	(6.4)	15	8.05
>=8% (>=64 mmol/mol)	22	(6.8)	38	11.95	18	(5.9)	23	7.70
Acute coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Acute myocardial infarction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	3	1.00
Angina pectoris								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Angina unstable								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Aortic valve calcification								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Aortic valve incompetence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Atrial fibrillation								
<8% (<64 mmol/mol)	4	(2.4)	4	2.38	0			
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.57	4	(1.3)	4	1.34
Atrial flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Atrial thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Atrioventricular block complete								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Bradycardia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Bundle branch block right								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	3	1.61
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac dysfunction								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Cardiac failure								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Cardiac failure chronic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Cardiac failure congestive								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Cardiac ventricular thrombosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Chronic coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Coronary artery disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	2	(0.7)	2	0.67
Coronary artery occlusion								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Diastolic dysfunction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Left atrial dilatation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Left ventricular dysfunction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Mitral valve incompetence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	2	(0.7)	2	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Palpitations								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Pericardial effusion								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Pericarditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Sinus arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Sinus bradycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Sinus tachycardia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Supraventricular extrasystoles								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Tachycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Tricuspid valve incompetence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Ventricular extrasystoles								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Congenital syphilitic osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hydrocele								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Type V hyperlipidaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	5	(1.6)	6	2.01
Ear inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Ear pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Eustachian tube dysfunction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Hypoacusis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Presbyacusis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Tinnitus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vertigo								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	4	1.34
Vertigo positional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	5	(1.6)	5	1.67
Goitre								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hyperplasia adrenal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hyperprolactinaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hyperthyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Thyroid mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Eye disorders								
All								
<8% (<64 mmol/mol)	5	(2.9)	10	5.96	14	(7.4)	16	8.59
>=8% (>=64 mmol/mol)	20	(6.2)	25	7.86	11	(3.6)	16	5.36
Acquired epiblepharon								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Asthenopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Astigmatism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Blepharitis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	3	1.61
>=8% (>=64 mmol/mol)	8	(2.5)	10	3.14	2	(0.7)	2	0.67
Conjunctival erosion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Conjunctivitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Dacryoadenitis acquired								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinopathy								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Diplopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Dry eye								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Eye discharge								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Eye inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Eye pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Macular oedema								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal tension glaucoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Ocular hypertension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Optic disc vascular disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Photophobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Post thrombotic retinopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Posterior capsule opacification								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Retinal aneurysm								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Retinal detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Retinal tear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Retinal vein occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Scintillating scotoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Uveitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Vision blurred								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vitreous haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	32	(18.8)	49	29.19	33	(17.6)	49	26.30
>=8% (>=64 mmol/mol)	51	(15.8)	87	27.36	41	(13.5)	65	21.76
Abdominal discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Abdominal distension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	0			
Abdominal pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	3	(1.0)	3	1.00
Abdominal pain lower								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Abdominal pain upper								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	3	(1.0)	4	1.34
Acid peptic disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Anal fissure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Anal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Chronic gastritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	2	(0.7)	2	0.67
Colitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Colitis ischaemic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Colitis microscopic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Constipation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	3	(1.0)	3	1.00
Crohn's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Dental caries								
<8% (<64 mmol/mol)	4	(2.4)	5	2.98	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.94	0			
Diarrhoea								
<8% (<64 mmol/mol)	16	(9.4)	19	11.32	10	(5.3)	11	5.90
>=8% (>=64 mmol/mol)	15	(4.7)	24	7.55	11	(3.6)	11	3.68
Diverticulum								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Diverticulum intestinal								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Dry mouth								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Duodenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Dyspepsia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Enteritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Enterocolitis								
<8% (<64 mmol/mol)	2	(1.2)	3	1.79	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Epigastric discomfort								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Flatulence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Food poisoning								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Frequent bowel movements								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Gastric disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Gastric polyps								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Gastrointestinal inflammation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	2	(0.7)	2	0.67
Haematochezia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Haemorrhoids								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Hiatus hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hyperaesthesia teeth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Hyperchlorhydria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Ileus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Inguinal hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Intra-abdominal haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Irritable bowel syndrome								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Large intestine polyp								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Loose tooth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Melaena								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Nausea								
<8% (<64 mmol/mol)	6	(3.5)	7	4.17	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	9	(2.8)	9	2.83	4	(1.3)	6	2.01
Oral discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Pancreatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Pancreatitis acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pancreatitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Periodontal inflammation								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Rectal polyp								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Rectal prolapse								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Stomatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Tooth disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Tooth impacted								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Toothache								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	7	(2.2)	7	2.20	2	(0.7)	2	0.67
Ulcerative gastritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Umbilical hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Vomiting								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	4	(1.3)	7	2.34
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	24	(14.1)	34	20.26	41	(21.8)	66	35.43
>=8% (>=64 mmol/mol)	51	(15.8)	80	25.15	37	(12.2)	44	14.73
Asthenia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	5	(2.7)	5	2.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Chest discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Chest pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Chills								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Death								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Discomfort								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Drug intolerance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Early satiety								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Fatigue								
<8% (<64 mmol/mol)	2	(1.2)	3	1.79	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	11	(3.4)	11	3.46	1	(0.3)	1	0.33
Feeling abnormal								
<8% (<64 mmol/mol)	1	(0.6)	3	1.79	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Feeling hot								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Gait disturbance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Hunger								
<8% (<64 mmol/mol)	5	(2.9)	6	3.57	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Implant site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Influenza like illness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Injection site bruising								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Injection site dermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Injection site erythema								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Injection site haemorrhage								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Injection site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Injection site hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Injection site mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Injection site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Injection site reaction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Injection site urticaria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Malaise								
<8% (<64 mmol/mol)	3	(1.8)	4	2.38	4	(2.1)	6	3.22
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	4	(1.3)	4	1.34
Medical device site bruise								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.57	0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	5	(2.7)	11	5.90
>=8% (>=64 mmol/mol)	1	(0.3)	4	1.26	3	(1.0)	3	1.00
Medical device site eczema								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Medical device site erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Medical device site haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Medical device site haemorrhage								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Medical device site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Medical device site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Medical device site pruritus								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Medical device site reaction								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	3	0.94	0			
Non-cardiac chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Oedema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Oedema peripheral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	4	(1.3)	5	1.67
Pain								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	3	(1.0)	3	1.00
Peripheral swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Procedural failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pyrexia								
<8% (<64 mmol/mol)	4	(2.4)	4	2.38	8	(4.3)	8	4.29
>=8% (>=64 mmol/mol)	13	(4.0)	14	4.40	13	(4.3)	14	4.69
Swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Thirst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vaccination site erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Vaccination site reaction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	4	(2.4)	5	2.98	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	5	(1.6)	7	2.20	3	(1.0)	4	1.34
Cholelithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Gallbladder cholesterolosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Hepatic cirrhosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hepatic cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Hepatic steatosis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	1	(0.3)	1	0.33
Hypertransaminasaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Liver disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Non-alcoholic steatohepatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Nonalcoholic fatty liver disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Steatohepatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<8% (<64 mmol/mol)	2	(1.2)	3	1.79	2	(1.1)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	3	1.00
Allergy to arthropod bite								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Immunisation reaction								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Seasonal allergy								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	3	1.00
Infections and infestations								
All								
<8% (<64 mmol/mol)	57	(33.5)	90	53.62	78	(41.5)	121	64.95
>=8% (>=64 mmol/mol)	112	(34.8)	173	54.40	115	(37.8)	166	55.57
Abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Acarodermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Acute sinusitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Anal abscess								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Bacterial infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Balanitis candida								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Breast abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Breast cellulitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Bronchitis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.89	0			
Candida infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Cellulitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Chlamydial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Chronic hepatitis C								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Chronic sinusitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Chronic tonsillitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Clostridium difficile infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Conjunctivitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Coronavirus infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	4	2.15
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
COVID-19								
<8% (<64 mmol/mol)	15	(8.8)	15	8.94	18	(9.6)	18	9.66
>=8% (>=64 mmol/mol)	34	(10.6)	34	10.69	43	(14.1)	44	14.73

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Cystitis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	6	(3.2)	7	3.76
>=8% (>=64 mmol/mol)	3	(0.9)	4	1.26	2	(0.7)	2	0.67
Dermatophytosis of nail								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Diverticulitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	1.00
Ear infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Empyema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Endophthalmitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Epididymitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Erysipelas								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Escherichia urinary tract infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Eye infection bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Folliculitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Fungal balanitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Fungal infection								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	1	(0.3)	1	0.33
Gastroenteritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	2	(0.7)	2	0.67
Gastroenteritis norovirus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Gastroenteritis viral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Gastrointestinal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Genital infection fungal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Giardiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.94	1	(0.3)	1	0.33
Helicobacter gastritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Helicobacter infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Herpes dermatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Herpes simplex								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Herpes virus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Herpes zoster								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	4	(1.3)	4	1.34

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hordeolum								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Infected bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Influenza								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Labyrinthitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Laryngitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Laryngopharyngitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Localised infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Lower respiratory tract infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	2	(0.7)	4	1.34
Lyme disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Mastitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Nail infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Nasopharyngitis								
<8% (<64 mmol/mol)	12	(7.1)	13	7.75	12	(6.4)	13	6.98
>=8% (>=64 mmol/mol)	18	(5.6)	23	7.23	22	(7.2)	24	8.03
Onychomycosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Oophoritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Oropharyngeal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Osteomyelitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Otitis externa								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Otitis media								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Otitis media acute								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Otitis media chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Parotitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Peri-implantitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Pericoronitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Periodontitis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	0				0			
Pharyngitis								
<8% (<64 mmol/mol)	6	(3.5)	7	4.17	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	5	(1.6)	6	1.89	5	(1.6)	7	2.34
Pharyngotonsillitis								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pneumonia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post procedural infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pulpitis dental								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Purulence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory syncytial virus infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory tract infection								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Respiratory tract infection viral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Rhinitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	4	(1.3)	4	1.34
Rotavirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Salpingitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Sepsis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Sinusitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	5	(1.6)	6	1.89	4	(1.3)	6	2.01
Skin bacterial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Skin infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Subcutaneous abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tinea infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Tonsillitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Tooth abscess								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Tooth infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Tracheitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Upper respiratory tract infection								
<8% (<64 mmol/mol)	10	(5.9)	14	8.34	6	(3.2)	7	3.76
>=8% (>=64 mmol/mol)	13	(4.0)	16	5.03	7	(2.3)	7	2.34
Urethritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Urinary tract infection								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	8	(4.3)	9	4.83
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	8	(2.6)	8	2.68
Vaginal infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Varicella								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Viral infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	3	(1.0)	3	1.00
Viral pharyngitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Viral upper respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Vulvovaginal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.94	4	(1.3)	4	1.34

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	25	(14.7)	27	16.09	18	(9.6)	23	12.35
>=8% (>=64 mmol/mol)	35	(10.9)	38	11.95	22	(7.2)	29	9.71
Accidental overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Animal bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Ankle fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Arthropod sting								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Bone contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Burn oral cavity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Burns first degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Cervical vertebral fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Chillblains								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Contusion								
<8% (<64 mmol/mol)	2	(1.2)	3	1.79	4	(2.1)	4	2.15
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Deafness traumatic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Endotracheal intubation complication								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Eye injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Fall								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Fibula fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Foot fracture								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Hand fracture								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				0			
Heat illness								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Hip fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Injury								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				0			
Joint injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Ligament sprain								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Limb injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Lower limb fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Meniscus injury								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Muscle strain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Post procedural fistula								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Post procedural haemorrhage								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Post procedural stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Post procedural swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Procedural pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Radius fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Rib fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Scar								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Skin abrasion								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Skin laceration								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Soft tissue injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Thermal burn								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Traumatic haematoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Vaccination complication								
<8% (<64 mmol/mol)	4	(2.4)	4	2.38	7	(3.7)	8	4.29
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.89	6	(2.0)	11	3.68
Wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Investigations								
All								
<8% (<64 mmol/mol)	8	(4.7)	10	5.96	7	(3.7)	7	3.76
>=8% (>=64 mmol/mol)	13	(4.0)	14	4.40	14	(4.6)	15	5.02
Alanine aminotransferase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Blood cholesterol increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Blood creatine increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Blood creatine phosphokinase increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Blood glucose increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Blood pressure decreased								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Blood pressure increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Blood triglycerides increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Body temperature increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac stress test abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram repolarisation abnormality								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Glycosylated haemoglobin increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hepatic enzyme increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
International normalised ratio abnormal								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio decreased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio increased								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				0			
Lipids increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Red blood cell count decreased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Transferrin saturation decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Weight decreased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Weight increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	9	(3.0)	9	3.01
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	15	(8.8)	16	9.53	14	(7.4)	16	8.59
>=8% (>=64 mmol/mol)	26	(8.1)	31	9.75	32	(10.5)	44	14.73
Appetite disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Decreased appetite								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Dehydration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Diabetes mellitus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Dyslipidaemia								
<8% (<64 mmol/mol)	5	(2.9)	5	2.98	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	4	(1.3)	4	1.34
Electrolyte imbalance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Fluid retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Gout								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	2	(0.7)	2	0.67
Hypercholesterolaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperglycaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				5	(1.6)	5	1.67
Hyperkalaemia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	3	(0.9)	4	1.26	3	(1.0)	3	1.00
Hyperlipidaemia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	3	1.00
Hypertriglyceridaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.89	3	(1.0)	3	1.00
Hyperuricaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemia								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.94	7	(2.3)	18	6.03
Hypokalaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Increased appetite								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Iron deficiency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Malnutrition								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Metabolic disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Obesity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vitamin D deficiency								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Zinc deficiency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	39	(22.9)	68	40.51	31	(16.5)	47	25.23
>=8% (>=64 mmol/mol)	60	(18.6)	88	27.67	61	(20.1)	86	28.79
Arthralgia								
<8% (<64 mmol/mol)	13	(7.6)	16	9.53	6	(3.2)	6	3.22
>=8% (>=64 mmol/mol)	10	(3.1)	11	3.46	11	(3.6)	13	4.35
Arthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Axillary mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Back disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Back pain								
<8% (<64 mmol/mol)	14	(8.2)	15	8.94	7	(3.7)	8	4.29
>=8% (>=64 mmol/mol)	13	(4.0)	14	4.40	17	(5.6)	17	5.69
Bone cyst								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Bursitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Cervical spinal stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Chondropathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Coccydynia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Costochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Dupuytren's contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Exostosis								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Fibromyalgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Fistula								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Flank pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Groin pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Intervertebral disc disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	2	(1.2)	3	1.79	1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	2	(0.7)	2	0.67
Joint effusion								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Joint swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Limb deformity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Lumbar spinal stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Mastication disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.67
Muscle contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Muscle spasms								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.89	2	(0.7)	2	0.67
Muscular weakness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal chest pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Musculoskeletal pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Myalgia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Myositis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Neck pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	3	(1.0)	3	1.00
Osteoarthritis								
<8% (<64 mmol/mol)	4	(2.4)	5	2.98	2	(1.1)	3	1.61
>=8% (>=64 mmol/mol)	8	(2.5)	9	2.83	7	(2.3)	7	2.34
Osteochondrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Osteopenia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Pain in extremity								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	12	(3.7)	13	4.09	8	(2.6)	11	3.68
Periarthritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	2	(0.7)	2	0.67
Plantar fasciitis								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Polyarthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Rotator cuff syndrome								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal osteoarthritis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Spinal pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Spinal stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Synovial cyst								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Tendonitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Tenosynovitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	4	2.15
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Tenosynovitis stenosans								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Trigger finger								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	4	1.34
Vertebral osteophyte								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	5	(2.9)	6	3.57	3	(1.6)	5	2.68
>=8% (>=64 mmol/mol)	6	(1.9)	7	2.20	2	(0.7)	4	1.34
Acrochordon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Basal cell carcinoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Colon cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Dysplastic naevus								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Glioblastoma multiforme								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Haemangioma of liver								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatocellular carcinoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Malignant melanoma in situ								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Metastases to liver								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Neoplasm skin								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Oral fibroma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Ovarian cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pancreatic neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Prostate cancer								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Renal cell carcinoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Salivary gland neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Seborrhoeic keratosis								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Nervous system disorders								
All								
<8% (<64 mmol/mol)	25	(14.7)	32	19.07	29	(15.4)	39	20.93
>=8% (>=64 mmol/mol)	40	(12.4)	55	17.29	38	(12.5)	46	15.40
Ageusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Anosmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Balance disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Brain injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Burning sensation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Carotid arteriosclerosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	2	(0.7)	2	0.67
Cerebral atrophy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Cerebral haemorrhage								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Cerebrovascular disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Cervical radiculopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Diabetic neuropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dizziness								
<8% (<64 mmol/mol)	4	(2.4)	6	3.57	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	8	(2.5)	10	3.14	12	(3.9)	13	4.35
Dizziness postural								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Dysgeusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Headache								
<8% (<64 mmol/mol)	8	(4.7)	8	4.77	11	(5.9)	17	9.12
>=8% (>=64 mmol/mol)	8	(2.5)	10	3.14	6	(2.0)	7	2.34
Hypoaesthesia								
<8% (<64 mmol/mol)	2	(1.2)	4	2.38	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	2	(0.7)	3	1.00
Lethargy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Lumbar radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	3	(1.0)	3	1.00
Memory impairment								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Mental impairment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Migraine								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Neuralgia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Neuroglycopenia								
<8% (<64 mmol/mol)	0				1	(0.5)	3	1.61
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Paraesthesia								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	0			
Parkinsonian gait								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Presyncope								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Sciatica								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	3	(1.0)	4	1.34
Somnolence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Syncope								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	1.26	1	(0.3)	1	0.33
Tension headache								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Thrombotic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Transient ischaemic attack								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Tremor								
<8% (<64 mmol/mol)	3	(1.8)	4	2.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Trigeminal neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vertebral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	7	(4.1)	7	4.17	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	8	(2.5)	9	2.83	8	(2.6)	8	2.68
Anxiety								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Bruxism								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Depressed mood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Depression								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	2	(0.7)	2	0.67
Insomnia								
<8% (<64 mmol/mol)	4	(2.4)	4	2.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	3	(1.0)	3	1.00
Mood swings								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Nightmare								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Persistent depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Sleep disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	5	(2.9)	7	4.17	10	(5.3)	10	5.37
>=8% (>=64 mmol/mol)	9	(2.8)	11	3.46	10	(3.3)	12	4.02
Acute kidney injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Chronic kidney disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Diabetic nephropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Dysuria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Haematuria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Nephrolithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Nocturia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pollakiuria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Pyelocaliectasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Renal colic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Renal cyst								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				0			
Renal impairment								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Ureterolithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urinary incontinence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Urinary retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Urinary tract obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Urine odour abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	2	(1.1)	4	2.15
>=8% (>=64 mmol/mol)	8	(2.5)	8	2.52	5	(1.6)	5	1.67
Atrophic vulvovaginitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Breast mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Breast pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Erectile dysfunction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Galactorrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Menopausal symptoms								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Penile rash								
<8% (<64 mmol/mol)	0				1	(0.5)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Pruritus genital								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Uterine polyp								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Uterine prolapse								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Vulvovaginal dryness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Vulvovaginal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	18	(10.6)	25	14.90	18	(9.6)	26	13.96
>=8% (>=64 mmol/mol)	27	(8.4)	34	10.69	20	(6.6)	26	8.70
Acquired diaphragmatic eventration								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Acute pulmonary oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Acute respiratory failure								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Allergic bronchitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Asthma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Bronchiectasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis chronic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Chronic obstructive pulmonary disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Cough								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	4	2.15
>=8% (>=64 mmol/mol)	9	(2.8)	9	2.83	5	(1.6)	5	1.67
Dyspnoea								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	1.00
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Emphysema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Epistaxis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.67
Haemoptysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Interstitial lung disease								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Laryngeal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Nasal congestion								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Nasal dryness								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Nasal turbinate hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Oropharyngeal pain								
<8% (<64 mmol/mol)	5	(2.9)	6	3.57	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.57	5	(1.6)	6	2.01

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paranasal sinus discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pleural effusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Pleuritic pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Productive cough								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Pulmonary embolism								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Pulmonary fibrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Pulmonary mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Respiratory disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	0				0			
Respiratory failure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Rhinitis allergic								
<8% (<64 mmol/mol)	0				1	(0.5)	5	2.68
>=8% (>=64 mmol/mol)	0				0			
Rhinorrhoea								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	2	(0.7)	2	0.67
Sinus congestion								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Sinus pain								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				0			
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sneezing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Throat irritation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	16	(9.4)	16	9.53	16	(8.5)	22	11.81
>=8% (>=64 mmol/mol)	26	(8.1)	28	8.80	26	(8.6)	33	11.05
Actinic keratosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Alopecia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	1	(0.3)	1	0.33
Alopecia areata								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Angioedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Asteatosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Blister								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Cold sweat								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				0			
Cold urticaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Dermal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Dermatitis allergic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Dermatitis contact								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.57	5	(1.6)	5	1.67
Diabetic foot								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Drug eruption								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Dry skin								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Ecchymosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Eczema								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	0			
Erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Granuloma annulare								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Haemorrhage subcutaneous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hyperhidrosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Hyperkeratosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Ingrowing nail								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lentigo								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Lipodystrophy acquired								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Lipohypertrophy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Macule								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Miliaria								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.61
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Myxoid cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Night sweats								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Pruritus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	2	(0.7)	2	0.67
Psoriasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Purpura								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Rash								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	5	(1.6)	5	1.67
Skin exfoliation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Skin fissures								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Skin irritation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin lesion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Skin ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Urticaria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	1.07
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Urticaria contact								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Urticaria thermal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	2	(0.7)	2	0.67
Knee operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Large intestinal polypectomy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Removal of foreign body								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Vascular disorders								
All								
<8% (<64 mmol/mol)	10	(5.9)	13	7.75	10	(5.3)	12	6.44
>=8% (>=64 mmol/mol)	22	(6.8)	24	7.55	15	(4.9)	17	5.69
Aortic arteriosclerosis								
<8% (<64 mmol/mol)	2	(1.2)	2	1.19	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Aortic stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Blood pressure inadequately controlled								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Brachiocephalic arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Flushing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Hypertension								
<8% (<64 mmol/mol)	3	(1.8)	3	1.79	4	(2.1)	5	2.68
>=8% (>=64 mmol/mol)	10	(3.1)	10	3.14	6	(2.0)	6	2.01
Hypertensive crisis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Hypertensive urgency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Hypotension								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.94	1	(0.3)	1	0.33
Iliac artery stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Intermittent claudication								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	0				0			
Macroangiopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.33
Peripheral arterial occlusive disease								
<8% (<64 mmol/mol)	1	(0.6)	2	1.19	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.67
Peripheral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.63	0			
Peripheral coldness								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	1	(0.5)	1	0.54
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.63	0			
Peripheral vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Peripheral venous disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33
Superficial vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	0			
Thrombosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.60	0			
>=8% (>=64 mmol/mol)	0				0			
Varicose vein								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.31	1	(0.3)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.22 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	126				125			
>=8% (>=64 mmol/mol)	136				138			
PYE (years)								
<8% (<64 mmol/mol)	75.04				72.76			
>=8% (>=64 mmol/mol)	80.20				80.01			
Events								
<8% (<64 mmol/mol)	76	(60.3)	233	310.48	55	(44.0)	116	159.43
>=8% (>=64 mmol/mol)	85	(62.5)	233	290.51	79	(57.2)	212	264.96
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	3	3.74	1	(0.7)	1	1.25
Anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	3	3.74	0			
Thrombocytosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
<8% (<64 mmol/mol)	1	(0.8)	2	2.67	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	4	(2.9)	5	6.23	1	(0.7)	1	1.25
Acute myocardial infarction								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Atrial fibrillation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Bradycardia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Cardiac failure congestive								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Coronary artery disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Supraventricular tachycardia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	3	(2.2)	3	3.75
Deafness unilateral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Ear pain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Hypoacusis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Tinnitus								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Vertigo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Endocrine disorders								
All								
<8% (<64 mmol/mol)	0				2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Adrenocortical insufficiency acute								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Hypothyroidism								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Inappropriate antidiuretic hormone secretion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Eye disorders								
All								
<8% (<64 mmol/mol)	12	(9.5)	13	17.32	8	(6.4)	10	13.74
>=8% (>=64 mmol/mol)	15	(11.0)	18	22.44	17	(12.3)	20	25.00
Astigmatism								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	4	(2.9)	4	5.00
Cataract nuclear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	2	(1.4)	2	2.50
Diabetic retinopathy								
<8% (<64 mmol/mol)	3	(2.4)	3	4.00	6	(4.8)	6	8.25
>=8% (>=64 mmol/mol)	7	(5.1)	8	9.97	10	(7.2)	11	13.75
Dry age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Dry eye								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Epiretinal membrane								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Eye irritation								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Glaucoma								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Lacrimation increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Macular oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Myopia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ocular hyperaemia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Ocular hypertension								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Presbyopia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Retinal exudates								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Retinal haemorrhage								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal vein occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Vision blurred								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Visual acuity reduced								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Vitreous haemorrhage								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	22	(17.5)	33	43.97	10	(8.0)	12	16.49
>=8% (>=64 mmol/mol)	16	(11.8)	27	33.66	22	(15.9)	30	37.49
Abdominal pain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Abdominal pain lower								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Abdominal pain upper								
<8% (<64 mmol/mol)	1	(0.8)	3	4.00	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Chronic gastritis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Constipation								
<8% (<64 mmol/mol)	3	(2.4)	4	5.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	3	3.74	0			
Dental caries								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Diarrhoea								
<8% (<64 mmol/mol)	8	(6.3)	8	10.66	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	6	(4.4)	9	11.22	8	(5.8)	8	10.00
Diverticulum								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Dyspepsia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Flatulence								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Food poisoning								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	2	2.75
>=8% (>=64 mmol/mol)	0				0			
Gastric dysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Gastric mucosal hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Gastric polyps								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Gastritis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal angiodysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Gingival bleeding								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Haemorrhoids								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Hiatus hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Hyperaesthesia teeth								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Intra-abdominal haematoma								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Large intestine polyp								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Nausea								
<8% (<64 mmol/mol)	4	(3.2)	4	5.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	4	(2.9)	4	5.00
Pancreatic pseudocyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Tongue rough								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Toothache								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	2	(1.4)	4	5.00
Vomiting								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	2	(1.4)	2	2.50
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	14	(11.1)	20	26.65	9	(7.2)	10	13.74
>=8% (>=64 mmol/mol)	11	(8.1)	16	19.95	10	(7.2)	11	13.75
Asthenia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Chest discomfort								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Chest pain								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Chills								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Condition aggravated								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Fatigue								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	2	2.49	3	(2.2)	3	3.75
Hunger								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Influenza like illness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Injection site reaction								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Injection site swelling								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Malaise								
<8% (<64 mmol/mol)	0				2	(1.6)	3	4.12
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Medical device site bruise								
<8% (<64 mmol/mol)	1	(0.8)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site erythema								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Medical device site pruritus								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site rash								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Medical device site reaction								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oedema peripheral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Pain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Pyrexia								
<8% (<64 mmol/mol)	4	(3.2)	4	5.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	4	(2.9)	4	5.00
Vaccination site pain								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	1	(0.7)	2	2.49	3	(2.2)	3	3.75
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Alcoholic liver disease								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Gallbladder polyp								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Hepatic cirrhosis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Immune system disorders								
All								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	3	(2.2)	3	3.75
Allergy to arthropod bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Allergy to arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Anaphylactic reaction								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Seasonal allergy								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infections and infestations								
All								
<8% (<64 mmol/mol)	35	(27.8)	43	57.30	18	(14.4)	23	31.61
>=8% (>=64 mmol/mol)	41	(30.1)	55	68.58	31	(22.5)	43	53.74
Abscess limb								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Anal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Bronchitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Campylobacter gastroenteritis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Cellulitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	2	2.50
Conjunctivitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
COVID-19								
<8% (<64 mmol/mol)	6	(4.8)	6	8.00	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	5	(3.6)	5	6.25
COVID-19 pneumonia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Cystitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	2	2.50
Ear infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Enteritis infectious								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Eye infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Folliculitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Fungal infection								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.8)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Fungal skin infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Gastroenteritis								
<8% (<64 mmol/mol)	4	(3.2)	4	5.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Gastrointestinal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Helicobacter infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Herpes zoster								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Influenza								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	2	(1.6)	3	4.12
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Kidney infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Localised infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Nasopharyngitis								
<8% (<64 mmol/mol)	10	(7.9)	13	17.32	3	(2.4)	6	8.25
>=8% (>=64 mmol/mol)	12	(8.8)	15	18.70	7	(5.1)	8	10.00
Onychomycosis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Otitis media								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Paraspinal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Peritonsillar abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumonia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Pulpitis dental								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Pustule								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Rhinitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	3	3.75
Sinusitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Soft tissue infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Subcutaneous abscess								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Tinea pedis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Tinea versicolour								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Tonsillitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Tooth abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Tooth infection								
<8% (<64 mmol/mol)	0				2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	2	2.49	1	(0.7)	1	1.25
Upper respiratory tract infection								
<8% (<64 mmol/mol)	3	(2.4)	4	5.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	5	(3.7)	7	8.73	3	(2.2)	3	3.75
Urinary tract infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	4	(2.9)	5	6.23	3	(2.2)	3	3.75
Vaginal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella zoster virus infection								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Vulvitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Vulvovaginal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Wound infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	18	(14.3)	27	35.98	10	(8.0)	10	13.74
>=8% (>=64 mmol/mol)	9	(6.6)	12	14.96	12	(8.7)	16	20.00
Accidental overdose								
<8% (<64 mmol/mol)	3	(2.4)	3	4.00	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Arthropod bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Bone contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Contusion								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Craniocerebral injury								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Face injury								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Facial bones fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Fall								
<8% (<64 mmol/mol)	3	(2.4)	3	4.00	1	(0.8)	1	1.37

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Foot fracture								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Hand fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Heat illness								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Intentional overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Joint injury								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Ligament sprain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Limb injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	2	2.50
Muscle contusion								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Muscle injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Overdose								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Rib fracture								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Road traffic accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Skin abrasion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Skin laceration								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Stab wound								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Subcutaneous haematoma								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Tendon injury								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Tendon rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Thermal burn								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Tibia fracture								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Underdose								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Vaccination complication								
<8% (<64 mmol/mol)	4	(3.2)	8	10.66	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Wound								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
<8% (<64 mmol/mol)	3	(2.4)	3	4.00	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	3	(2.2)	4	5.00
Alanine aminotransferase increased								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Blood creatinine increased								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Blood potassium increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Intraocular pressure increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Liver function test abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	2	2.50
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	4	(3.2)	4	5.33	6	(4.8)	7	9.62
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	5	(3.6)	9	11.25
Abnormal weight gain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Hyperammonaemia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Hypercholesterolaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Hyperglycaemia								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Hyperkalaemia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Hyperlipidaemia								
<8% (<64 mmol/mol)	0				2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Hyperuricaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Hypoglycaemia								
<8% (<64 mmol/mol)	0				2	(1.6)	3	4.12
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	5	6.25
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	20	(15.9)	27	35.98	11	(8.8)	16	21.99
>=8% (>=64 mmol/mol)	18	(13.2)	33	41.15	18	(13.0)	29	36.25
Arthralgia								
<8% (<64 mmol/mol)	2	(1.6)	3	4.00	5	(4.0)	6	8.25
>=8% (>=64 mmol/mol)	4	(2.9)	4	4.99	5	(3.6)	7	8.75
Arthritis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Axillary mass								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Back pain								
<8% (<64 mmol/mol)	5	(4.0)	5	6.66	4	(3.2)	5	6.87
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	7	(5.1)	8	10.00
Bursitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Flank pain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Intervertebral disc disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Muscle spasms								
<8% (<64 mmol/mol)	6	(4.8)	6	8.00	0			
>=8% (>=64 mmol/mol)	3	(2.2)	5	6.23	1	(0.7)	1	1.25
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Myalgia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	2	(1.4)	2	2.50
Neck pain								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Osteoarthritis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Osteoporosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Pain in extremity								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	3	(2.4)	4	5.50
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	2	(1.4)	2	2.50
Periarthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Plantar fasciitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Polymyalgia rheumatica								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	3	3.75
Rheumatoid arthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Rotator cuff syndrome								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Soft tissue swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	3	3.74	0			
Spinal stenosis								
<8% (<64 mmol/mol)	2	(1.6)	4	5.33	0			
>=8% (>=64 mmol/mol)	0				0			
Tendonitis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	3	3.74	0			
Tenosynovitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Trigger finger								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	2	(1.4)	2	2.50
Breast cancer								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Chronic myeloid leukaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Colon adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Colon cancer stage II								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Gastric cancer								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Lymphangioma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Pancreatic carcinoma metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Nervous system disorders								
All								
<8% (<64 mmol/mol)	13	(10.3)	24	31.98	7	(5.6)	10	13.74
>=8% (>=64 mmol/mol)	14	(10.3)	18	22.44	18	(13.0)	24	30.00
Autonomic nervous system imbalance								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Burning sensation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Carotid artery aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cerebral infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Cervicobrachial syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Diabetic neuropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Dizziness								
<8% (<64 mmol/mol)	4	(3.2)	5	6.66	5	(4.0)	6	8.25
>=8% (>=64 mmol/mol)	0				4	(2.9)	7	8.75
Facial paralysis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Headache								
<8% (<64 mmol/mol)	6	(4.8)	11	14.66	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	8	(5.9)	9	11.22	8	(5.8)	9	11.25
Hypoaesthesia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Migraine								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	0				0			
Neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Peripheral paralysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Piriformis syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Restless legs syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sciatica								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	1	(0.7)	1	1.25
Somnolence								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Syncope								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Tension headache								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Thalamic infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Thrombotic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.4)	2	2.50
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	2	(1.5)	3	3.74	3	(2.2)	3	3.75
Adjustment disorder								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Depression								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	2	(1.4)	2	2.50
Insomnia								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Major depression								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Sleep disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	6	(4.8)	8	10.66	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Bladder prolapse								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Diabetic nephropathy								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Hydronephrosis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Nephrotic syndrome								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Pollakiuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Polyuria								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Renal cyst								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Renal impairment								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Urethral stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Urine odour abnormal								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	1	(0.7)	1	1.25
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Cervical polyp								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Erectile dysfunction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Prostatitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Pruritus genital								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	7	(5.6)	12	15.99	0			
>=8% (>=64 mmol/mol)	8	(5.9)	17	21.20	4	(2.9)	5	6.25
Acute respiratory failure								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Chronic obstructive pulmonary disease								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Cough								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	1	(0.7)	2	2.49	0			
Epistaxis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(2.2)	7	8.73	0			
Nasal congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Nasal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal septum deviation								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Oropharyngeal pain								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				2	(1.4)	3	3.75
Productive cough								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Respiratory failure								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Rhinorrhoea								
<8% (<64 mmol/mol)	2	(1.6)	4	5.33	0			
>=8% (>=64 mmol/mol)	3	(2.2)	3	3.74	1	(0.7)	1	1.25
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Sneezing								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	6	(4.8)	6	8.00	4	(3.2)	4	5.50
>=8% (>=64 mmol/mol)	7	(5.1)	8	9.97	2	(1.4)	2	2.50
Alopecia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Blister								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Dermal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Dermatitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Eczema								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			
Hyperhidrosis								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Miliaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	0			
Neurodermatitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.37
>=8% (>=64 mmol/mol)	0				0			
Pruritus								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Rash								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	2	(1.5)	2	2.49	1	(0.7)	1	1.25
Rash papular								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			
Urticaria								
<8% (<64 mmol/mol)	2	(1.6)	2	2.67	0			
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Toe amputation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.7)	1	1.25
Vascular disorders								
All								
<8% (<64 mmol/mol)	4	(3.2)	4	5.33	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	3	(2.2)	3	3.75
Hypertension								
<8% (<64 mmol/mol)	3	(2.4)	3	4.00	2	(1.6)	2	2.75
>=8% (>=64 mmol/mol)	1	(0.7)	1	1.25	3	(2.2)	3	3.75
Orthostatic hypotension								
<8% (<64 mmol/mol)	1	(0.8)	1	1.33	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:11:09 - taesocptgrptrl/taesocptgrphba1csumontow2sas.txt

7.16.23 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	117				120			
>=8% (>=64 mmol/mol)	174				171			
PYE (years)								
<8% (<64 mmol/mol)	68.43				68.87			
>=8% (>=64 mmol/mol)	98.93				97.92			
Events								
<8% (<64 mmol/mol)	76	(65.0)	196	286.41	73	(60.8)	277	402.19
>=8% (>=64 mmol/mol)	95	(54.6)	259	261.80	94	(55.0)	273	278.79
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	5	(2.9)	5	5.05	4	(2.3)	4	4.08
Anaemia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	2	(1.2)	2	2.04
Blood loss anaemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Eosinophilia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Iron deficiency anaemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Lymphadenopathy mediastinal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Cardiac disorders								
All								
<8% (<64 mmol/mol)	1	(0.9)	2	2.92	7	(5.8)	11	15.97
>=8% (>=64 mmol/mol)	6	(3.4)	6	6.06	7	(4.1)	11	11.23
Acute myocardial infarction								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Angina pectoris								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Aortic valve calcification								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Aortic valve sclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Atrial enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Atrial fibrillation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Bundle branch block left								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Bundle branch block right								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Cardiac failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	2	2.04
Cardiac failure congestive								
<8% (<64 mmol/mol)	0				2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	0				0			
Cardiac perfusion defect								
<8% (<64 mmol/mol)	0				1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	0				0			
Coronary artery disease								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Left atrial enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Myocardial ischaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Palpitations								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Pericarditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Sinus bradycardia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Tachycardia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Corneal dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	0				3	(1.8)	3	3.06
Cerumen impaction								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Ear discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Middle ear inflammation								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Vertigo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Adrenocortical insufficiency acute								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hypogonadism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hypothyroidism								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Eye disorders								
All								
<8% (<64 mmol/mol)	13	(11.1)	17	24.84	17	(14.2)	32	46.46
>=8% (>=64 mmol/mol)	13	(7.5)	16	16.17	21	(12.3)	25	25.53
Age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Astigmatism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Cataract								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	3	(1.8)	5	5.11
Corneal erosion								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	3	3.06
Diabetic retinopathy								
<8% (<64 mmol/mol)	6	(5.1)	7	10.23	8	(6.7)	8	11.62
>=8% (>=64 mmol/mol)	6	(3.4)	7	7.08	7	(4.1)	7	7.15
Diplopia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Eye discharge								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye inflammation								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Eye pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Macular degeneration								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Macular oedema								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Meibomianitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Open angle glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	2	2.04
Presbyopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Retinal deposits								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Retinal detachment								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Retinal drusen								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Retinal exudates								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Retinal haemorrhage								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Retinal scar								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal vascular disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Retinopathy hypertensive								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				3	(1.8)	3	3.06

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Visual impairment								
<8% (<64 mmol/mol)	0				1	(0.8)	9	13.07
>=8% (>=64 mmol/mol)	0				0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Vitreous haemorrhage								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	19	(16.2)	23	33.61	14	(11.7)	22	31.94
>=8% (>=64 mmol/mol)	16	(9.2)	27	27.29	21	(12.3)	27	27.57
Abdominal discomfort								
<8% (<64 mmol/mol)	0				1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Abdominal distension								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Abdominal pain								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	0				4	(2.3)	4	4.08
Abdominal pain upper								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Chronic gastritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	1	(0.6)	1	1.02
Constipation								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Dental caries								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				3	(1.8)	3	3.06
Diarrhoea								
<8% (<64 mmol/mol)	8	(6.8)	8	11.69	5	(4.2)	5	7.26
>=8% (>=64 mmol/mol)	7	(4.0)	10	10.11	4	(2.3)	4	4.08
Eructation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Faeces pale								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Food poisoning								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Gingival disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Hypoaesthesia oral								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	3	3.03	0			
Nausea								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	3	(1.8)	3	3.06
Pancreatic duct dilatation								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatic failure								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Proctalgia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Toothache								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Upper gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Vomiting								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	3	(1.7)	5	5.05	1	(0.6)	1	1.02
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	11	(9.4)	14	20.46	19	(15.8)	26	37.75
>=8% (>=64 mmol/mol)	15	(8.6)	24	24.26	7	(4.1)	10	10.21
Asthenia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Axillary pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	0			
Cyst								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Discomfort								
<8% (<64 mmol/mol)	0				1	(0.8)	8	11.62
>=8% (>=64 mmol/mol)	0				0			
Facial pain								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Fatigue								
<8% (<64 mmol/mol)	1	(0.9)	2	2.92	0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	1	(0.6)	1	1.02
Feeling abnormal								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	0			
>=8% (>=64 mmol/mol)	0				0			
Inflammation								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Injection site pain								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Injection site rash								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Injection site reaction								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Malaise								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	2	2.04
Medical device site dermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Medical device site erythema								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Medical device site pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Medical device site reaction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Multiple organ dysfunction syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Oedema								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Oedema due to renal disease								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Oedema peripheral								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Pain								
<8% (<64 mmol/mol)	2	(1.7)	3	4.38	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Peripheral swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Pyrexia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	5	(4.2)	5	7.26
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	1	(0.6)	2	2.04
Thirst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Vaccination site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	1	(0.6)	1	1.02
Vaccination site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Xerosis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	4	5.81
>=8% (>=64 mmol/mol)	1	(0.6)	2	2.02	2	(1.2)	2	2.04
Biliary dyskinesia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Cholecystitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Gallbladder polyp								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hepatic steatosis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hepatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hyperplastic cholecystopathy								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Liver disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Drug hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hypersensitivity								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Seasonal allergy								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Infections and infestations								
All								
<8% (<64 mmol/mol)	35	(29.9)	44	64.30	35	(29.2)	52	75.50
>=8% (>=64 mmol/mol)	52	(29.9)	73	73.79	44	(25.7)	68	69.44
Abscess								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Bacteraemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Breast abscess								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Bronchitis								
<8% (<64 mmol/mol)	3	(2.6)	3	4.38	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	5	(2.9)	5	5.05	1	(0.6)	1	1.02
Candida infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Cellulitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Cholecystitis infective								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctivitis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Coronavirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	2	2.04
COVID-19								
<8% (<64 mmol/mol)	5	(4.3)	5	7.31	9	(7.5)	9	13.07
>=8% (>=64 mmol/mol)	21	(12.1)	21	21.23	14	(8.2)	16	16.34
COVID-19 pneumonia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	1	(0.6)	1	1.02
Cystitis								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	1	(0.6)	1	1.02
Diabetic foot infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Eye infection								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	0				0			
Fungal infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Fungal skin infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Gastroenteritis								
<8% (<64 mmol/mol)	3	(2.6)	3	4.38	2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	4	(2.3)	4	4.04	3	(1.8)	3	3.06
Gastroenteritis viral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Herpes zoster								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Infected dermal cyst								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Influenza								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	4	(3.3)	5	7.26
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	4	(2.3)	5	5.11

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Localised infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Nasopharyngitis								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	7	(5.8)	9	13.07
>=8% (>=64 mmol/mol)	4	(2.3)	4	4.04	5	(2.9)	6	6.13
Oral herpes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	2	2.02	0			
Osteomyelitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Otitis media								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Otitis media acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Paronychia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	2	2.04
Periodontitis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Pharyngitis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	5	(2.9)	5	5.11
Pharyngotonsillitis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Pneumonia								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Pneumonia viral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Post procedural infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulmonary tuberculoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Pulpitis dental								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Respiratory syncytial virus infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory tract infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	2	(1.2)	2	2.04
Respiratory tract infection viral								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	3	3.03	4	(2.3)	5	5.11
Sepsis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Sinusitis								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	3	(1.7)	4	4.04	0			
Soft tissue infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Tooth abscess								
<8% (<64 mmol/mol)	0				2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Tooth infection								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Upper respiratory tract infection								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	4	(2.3)	4	4.08
Urinary tract infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	3	(1.8)	4	4.08
Viral infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Viral rhinitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral tracheitis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	8	(6.8)	12	17.54	12	(10.0)	17	24.68
>=8% (>=64 mmol/mol)	11	(6.3)	13	13.14	15	(8.8)	18	18.38
Accidental overdose								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	2	2.04
Accidental underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Animal bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Arthropod bite								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Arthropod sting								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Chillblains								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Concussion								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Contusion								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Crush injury								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Exposure to SARS-CoV-2								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Extra dose administered								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Fall								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Foot fracture								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Incorrect dose administered								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	1	(0.6)	2	2.04
Joint injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Ligament sprain								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Limb injury								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Medication error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Meniscus injury								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Muscle injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Muscle strain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Overdose								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Product administration error								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Skin abrasion								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Skin laceration								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Spinal column injury								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:11:11 - taesocptgrptrl/taesocptgrphba1csumontow4sas.txt

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Spinal compression fracture								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Subcutaneous haematoma								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Subdural haematoma								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Thermal burn								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Tooth fracture								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Vaccination complication								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Wound								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Wrong product administered								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	2	2.02	0			
Investigations								
All								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	9	(7.5)	10	14.52
>=8% (>=64 mmol/mol)	10	(5.7)	13	13.14	4	(2.3)	4	4.08
Amylase increased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Blood alkaline phosphatase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Blood creatinine increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Blood pressure increased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Blood triglycerides increased								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Blood urine present								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Catheterisation cardiac								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Electrocardiogram abnormal								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram T wave inversion								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Eosinophil count increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Glomerular filtration rate decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Haematocrit increased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Haemoglobin increased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Liver function test abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Liver function test increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Platelet count decreased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Transaminases increased								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Weight increased								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	5	(2.9)	5	5.05	3	(1.8)	3	3.06

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	7	(6.0)	8	11.69	12	(10.0)	13	18.88
>=8% (>=64 mmol/mol)	8	(4.6)	10	10.11	8	(4.7)	9	9.19
Decreased appetite								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Dehydration								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Dyslipidaemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	2	(1.1)	3	3.03	1	(0.6)	1	1.02
Fluid retention								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Hypercholesterolaemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Hyperglycaemia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				4	(2.3)	4	4.08
Hyperkalaemia								
<8% (<64 mmol/mol)	0				4	(3.3)	4	5.81
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hypertriglyceridaemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Hypoalbuminaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hypoglycaemia								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Hypokalaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Hyponatraemia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Increased appetite								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipomatosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Vitamin D deficiency								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	20	(17.1)	25	36.53	13	(10.8)	22	31.94
>=8% (>=64 mmol/mol)	12	(6.9)	16	16.17	22	(12.9)	26	26.55
Arthralgia								
<8% (<64 mmol/mol)	4	(3.4)	5	7.31	3	(2.5)	3	4.36
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	3	(1.8)	3	3.06
Arthritis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Back disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Back pain								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	6	(5.0)	6	8.71
>=8% (>=64 mmol/mol)	4	(2.3)	4	4.04	5	(2.9)	5	5.11
Bone cyst								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Bone pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Coccydynia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Flank pain								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Foot deformity								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Jaw disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle spasms								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	1	(0.6)	1	1.02
Myalgia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Myositis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Neck pain								
<8% (<64 mmol/mol)	3	(2.6)	3	4.38	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Osteoarthritis								
<8% (<64 mmol/mol)	4	(3.4)	4	5.85	4	(3.3)	5	7.26
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	3	(1.8)	3	3.06
Osteochondrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	2	2.04
Pain in extremity								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Periarthritis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Periostitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Rotator cuff syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Spinal osteoarthritis								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	0			
>=8% (>=64 mmol/mol)	0				0			
Tendon disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Tendonitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Tenosynovitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Torticollis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Trigger finger								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	3	(1.7)	3	3.03	3	(1.8)	5	5.11
Adrenal adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Eye naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Lung adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Osteoma								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatic neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Small cell lung cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Small intestine neuroendocrine tumour								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Uterine cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Nervous system disorders								
All								
<8% (<64 mmol/mol)	10	(8.5)	16	23.38	19	(15.8)	36	52.27
>=8% (>=64 mmol/mol)	9	(5.2)	16	16.17	10	(5.8)	11	11.23
Anosmia								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Basilar migraine								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				3	(1.8)	3	3.06
Cerebral arteriosclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Cerebrovascular accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Cerebrovascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Cognitive disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Diabetic neuropathy								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Dizziness								
<8% (<64 mmol/mol)	4	(3.4)	8	11.69	2	(1.7)	3	4.36
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Dizziness postural								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Dysgeusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Essential tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Facial nerve disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Headache								
<8% (<64 mmol/mol)	3	(2.6)	3	4.38	7	(5.8)	10	14.52
>=8% (>=64 mmol/mol)	5	(2.9)	7	7.08	2	(1.2)	2	2.04
Hemiparesis								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hypoaesthesia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic coma								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hyporeflexia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Memory impairment								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Migraine								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Morton's neuralgia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Paraesthesia								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Sciatica								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Sleep deficit								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Transient ischaemic attack								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Tremor								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	2	(1.7)	6	8.71
>=8% (>=64 mmol/mol)	0				0			
Vascular encephalopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	8	(4.7)	8	8.17
Affect lability								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Depression								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	2	2.04
Fear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Insomnia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Mental status changes								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Mixed anxiety and depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Phobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Sleep disorder								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	5	5.05	5	(2.9)	5	5.11
Acute kidney injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Chronic kidney disease								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Dysuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Haematuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	2	2.02	0			
Hydrocalyx								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Nephropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Renal colic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Renal cyst								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Menopausal disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Respiratory, thoracic and mediastinal disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	9	(7.7)	10	14.61	9	(7.5)	12	17.42
>=8% (>=64 mmol/mol)	8	(4.6)	10	10.11	10	(5.8)	11	11.23
Asthma								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Bronchitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Cough								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	3	(1.8)	3	3.06
Dyspnoea								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	3	(2.5)	4	5.81
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Emphysema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Epistaxis								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	2	2.90
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Nasal congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Nasal septum deviation								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Oropharyngeal pain								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Paranasal cyst								
<8% (<64 mmol/mol)	0				2	(1.7)	2	2.90
>=8% (>=64 mmol/mol)	0				0			
Pleurisy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Pulmonary fibrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Pulmonary hypertension								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Respiratory disorder								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	2	2.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Rhinorrhoea								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Sinus congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Sinus pain								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	8	(6.8)	8	11.69	6	(5.0)	7	10.16
>=8% (>=64 mmol/mol)	4	(2.3)	5	5.05	9	(5.3)	9	9.19
Alopecia								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Blister								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Dermatitis contact								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Eczema								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04
Hyperhidrosis								
<8% (<64 mmol/mol)	2	(1.7)	2	2.92	0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Hyperkeratosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Intertrigo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Lipohypertrophy								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pruritus								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	2	(1.2)	2	2.04
Rash								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Seborrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Skin reaction								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Skin ulcer								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Umbilical haematoma								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Urticaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	2	(1.1)	2	2.02	0			
Cardiac pacemaker replacement								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Shoulder operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Tooth extraction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Vascular disorders								
All								
<8% (<64 mmol/mol)	3	(2.6)	4	5.85	4	(3.3)	4	5.81
>=8% (>=64 mmol/mol)	5	(2.9)	8	8.09	12	(7.0)	15	15.32
Aortic arteriosclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.2)	2	2.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Blood pressure fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Deep vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Diabetic vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	1	1.02
Haematoma								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Hypertension								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	5	(2.9)	5	5.11
Hypertensive crisis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	1	(0.6)	3	3.06
Hypertensive urgency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02
Hypotension								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Neovascularisation								
<8% (<64 mmol/mol)	0				1	(0.8)	1	1.45
>=8% (>=64 mmol/mol)	0				0			
Orthostatic hypotension								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Peripheral arterial occlusive disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	1	1.01	0			
Peripheral artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.6)	3	3.03	0			
Peripheral venous disease								
<8% (<64 mmol/mol)	1	(0.9)	1	1.46	0			
>=8% (>=64 mmol/mol)	0				0			
Thrombophlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.6)	1	1.02

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.24 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	189				189			
>=8% (>=64 mmol/mol)	101				103			
PYE (years)								
<8% (<64 mmol/mol)	92.25				93.57			
>=8% (>=64 mmol/mol)	50.06				50.55			
Events								
<8% (<64 mmol/mol)	121	(64.0)	312	338.22	124	(65.6)	363	387.93
>=8% (>=64 mmol/mol)	68	(67.3)	195	389.52	66	(64.1)	256	506.47
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	2	3.96
Anaemia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Iron deficiency anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Lymphadenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Lymphadenopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Thrombocytopenia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
<8% (<64 mmol/mol)	7	(3.7)	7	7.59	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	1	(1.0)	2	3.96
Angina pectoris								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Angina unstable								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Atrial fibrillation								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Bundle branch block right								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Cardiac failure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Cardiomegaly								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiovascular disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Myocardial ischaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Palpitations								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Ventricular extrasystoles								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Deafness neurosensory								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Ear pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Vertigo								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Endocrine disorders								
All								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hypothyroidism								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Eye disorders								
All								
<8% (<64 mmol/mol)	18	(9.5)	25	27.10	15	(7.9)	20	21.37
>=8% (>=64 mmol/mol)	11	(10.9)	12	23.97	13	(12.6)	17	33.63
Arteriosclerotic retinopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Astigmatism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Cataract								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Cataract nuclear								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Corneal erosion								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Diabetic retinopathy								
<8% (<64 mmol/mol)	6	(3.2)	6	6.50	6	(3.2)	6	6.41
>=8% (>=64 mmol/mol)	6	(5.9)	6	11.99	8	(7.8)	8	15.83
Dry eye								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Epiretinal membrane								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	3	(2.9)	3	5.94
Macular oedema								
<8% (<64 mmol/mol)	2	(1.1)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Myopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Ocular hypertension								
<8% (<64 mmol/mol)	0				1	(0.5)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Photopsia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Posterior capsule opacification								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Presbyopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Pterygium								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal vascular disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Retinopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Retinopathy hypertensive								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			
Vision blurred								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Vitreous floaters								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	16	(8.5)	21	22.77	16	(8.5)	25	26.72
>=8% (>=64 mmol/mol)	10	(9.9)	17	33.96	8	(7.8)	16	31.65
Abdominal discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Abdominal distension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Abdominal pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Abdominal pain upper								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	1	(1.0)	1	1.98
Anal fissure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Chronic gastritis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Constipation								
<8% (<64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Dental caries								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Diarrhoea								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	2	(2.0)	3	5.99	2	(1.9)	3	5.94
Diverticulum intestinal								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Dyspepsia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Faeces soft								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Gastric polyps								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Gastritis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Gastritis erosive								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Gingival recession								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	3.96
Haemorrhoids								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hiatus hernia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Impaired gastric emptying								
<8% (<64 mmol/mol)	1	(0.5)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			
Irritable bowel syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lumbar hernia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Nausea								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	6	(3.2)	6	6.41
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	2	(1.9)	2	3.96
Odynophagia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Pancreatic failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Pneumatosis intestinalis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Toothache								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	4	7.91
Vomiting								
<8% (<64 mmol/mol)	5	(2.6)	5	5.42	5	(2.6)	5	5.34
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	29	(15.3)	35	37.94	20	(10.6)	63	67.33
>=8% (>=64 mmol/mol)	12	(11.9)	15	29.96	14	(13.6)	20	39.57
Asthenia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Chest pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Fatigue								
<8% (<64 mmol/mol)	3	(1.6)	4	4.34	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Hunger								
<8% (<64 mmol/mol)	0				1	(0.5)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hyperthermia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inflammation								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Influenza like illness								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Injection site mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Injection site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Injection site urticaria								
<8% (<64 mmol/mol)	1	(0.5)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			
Malaise								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	2	(1.1)	40	42.75
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	4	7.91
Medical device site bruise								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	3	5.94
Medical device site erythema								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	3.96
Medical device site haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Medical device site haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Medical device site irritation								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Medical device site pruritus								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	0				0			
Medical device site rash								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	4	(2.1)	4	4.34	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	3	(2.9)	3	5.94
Medical device site reaction								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	0			
>=8% (>=64 mmol/mol)	0				0			
Oedema peripheral								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Pain								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Pyrexia								
<8% (<64 mmol/mol)	6	(3.2)	7	7.59	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	2	(1.9)	2	3.96
Swelling face								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Vaccination site pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	5	(2.6)	6	6.50	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	0				0			
Gallbladder disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Gallbladder polyp								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Hepatic calcification								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatic steatosis								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hypertransaminasaemia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hypersensitivity								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Seasonal allergy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Infections and infestations								
All								
<8% (<64 mmol/mol)	66	(34.9)	86	93.23	67	(35.4)	99	105.80
>=8% (>=64 mmol/mol)	38	(37.6)	61	121.85	34	(33.0)	49	96.94
Abscess limb								
<8% (<64 mmol/mol)	0				1	(0.5)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Acute sinusitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Breast abscess								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Bronchitis								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	2	3.96
Conjunctivitis								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Coronavirus infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
COVID-19								
<8% (<64 mmol/mol)	19	(10.1)	20	21.68	20	(10.6)	22	23.51
>=8% (>=64 mmol/mol)	10	(9.9)	10	19.98	12	(11.7)	12	23.74
COVID-19 pneumonia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Cystitis escherichia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Eye infection								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Fungal skin infection								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Gastric infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Gastroenteritis								
<8% (<64 mmol/mol)	6	(3.2)	7	7.59	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Gastroenteritis viral								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal infection								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	3	3.21
>=8% (>=64 mmol/mol)	0				0			
Genital infection fungal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	2	4.00	0			
Gingivitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Herpes zoster								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hordeolum								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Infected cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Influenza								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	3	(2.9)	3	5.94

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Localised infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Lower respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Nasopharyngitis								
<8% (<64 mmol/mol)	20	(10.6)	22	23.85	25	(13.2)	32	34.20
>=8% (>=64 mmol/mol)	14	(13.9)	20	39.95	11	(10.7)	11	21.76
Norovirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Otitis externa								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Otitis media								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Periodontitis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Pharyngitis								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Pneumonia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Respiratory tract infection								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory tract infection viral								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Rhinitis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	3	5.94
Severe acute respiratory syndrome								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinusitis								
<8% (<64 mmol/mol)	4	(2.1)	4	4.34	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Skin infection								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Tinea cruris								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Tinea pedis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Tonsillitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Tooth abscess								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Tooth infection								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Upper respiratory tract infection								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	5	(4.9)	6	11.87
Urinary tract infection								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	4	(2.1)	6	6.41
>=8% (>=64 mmol/mol)	4	(4.0)	4	7.99	2	(1.9)	2	3.96
Vaginal infection								
<8% (<64 mmol/mol)	1	(0.5)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			
Viral infection								
<8% (<64 mmol/mol)	0				3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Vulvitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Vulvovaginitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Injury, poisoning and procedural complications								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	16	(8.5)	19	20.60	22	(11.6)	26	27.79
>=8% (>=64 mmol/mol)	14	(13.9)	18	35.96	11	(10.7)	13	25.72
Accidental overdose								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	4	(4.0)	5	9.99	0			
Anaemia postoperative								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Animal scratch								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Arthropod bite								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Back injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Burns first degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Clavicle fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Contusion								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Corneal abrasion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Epicondylitis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Face injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Fall								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Fibula fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Hand fracture								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Heat stroke								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Incorrect dose administered								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Joint injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Ligament sprain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	0			
Limb injury								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Medication error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Muscle strain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Nerve injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Prescribed overdose								
<8% (<64 mmol/mol)	4	(2.1)	4	4.34	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Procedural pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Product administration error								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Product dispensing error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Radius fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Road traffic accident								
<8% (<64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(1.0)	2	4.00	0			
Skin abrasion								
<8% (<64 mmol/mol)	1	(0.5)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Skin laceration								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Tooth fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Vaccination complication								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	6	(3.2)	8	8.55
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	2	(1.9)	3	5.94
Wound								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Wound dehiscence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Wrong product administered								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	3.96
Investigations								
All								
<8% (<64 mmol/mol)	12	(6.3)	13	14.09	9	(4.8)	11	11.76
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	4	(3.9)	4	7.91
Angiogram								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Blood cholesterol increased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Blood glucose increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Blood pressure increased								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood testosterone decreased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Blood triglycerides increased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Blood uric acid increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Cardiac murmur								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram abnormal								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Eosinophil count increased								
<8% (<64 mmol/mol)	0				1	(0.5)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Heart rate increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hepatic enzyme increased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hepatitis B virus test positive								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Lipids abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Low density lipoprotein increased								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Mycobacterium tuberculosis complex test positive								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Occult blood positive								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
SARS-CoV-2 test positive								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Weight decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Weight increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
White blood cell count decreased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	4.34	4	(2.1)	6	6.41
>=8% (>=64 mmol/mol)	4	(4.0)	6	11.99	5	(4.9)	5	9.89
Dehydration								
<8% (<64 mmol/mol)	0				1	(0.5)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Hypercholesterolaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Hyperuricaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hypoglycaemia								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	2	(1.1)	3	3.21
>=8% (>=64 mmol/mol)	3	(3.0)	5	9.99	1	(1.0)	1	1.98
Hyponatraemia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Insulin resistance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Obesity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Vitamin D deficiency								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Musculoskeletal and connective tissue disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	16	(8.5)	19	20.60	24	(12.7)	30	32.06
>=8% (>=64 mmol/mol)	11	(10.9)	12	23.97	15	(14.6)	33	65.29
Arthralgia								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	5	(2.6)	5	5.34
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	4	(3.9)	4	7.91
Arthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Back pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	7	(3.7)	8	8.55
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	4	(3.9)	17	33.63
Bursitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Chondromalacia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Groin pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Limb discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Limb mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Muscle spasms								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Muscular weakness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Myalgia								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	0				4	(3.9)	5	9.89
Neck pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nodal osteoarthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Osteoarthritis								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Pain in extremity								
<8% (<64 mmol/mol)	5	(2.6)	5	5.42	5	(2.6)	5	5.34
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Periarthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	3.96
Rheumatoid arthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Synovial cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Tendonitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Tenosynovitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Trigger finger								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	3	3.21
>=8% (>=64 mmol/mol)	3	(3.0)	3	5.99	0			
Benign neoplasm of thyroid gland								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Benign renal neoplasm								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Eye naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Haemangioma of liver								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Melanocytic naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Nervous system disorders								
All								
<8% (<64 mmol/mol)	20	(10.6)	27	29.27	18	(9.5)	22	23.51
>=8% (>=64 mmol/mol)	7	(6.9)	19	37.95	6	(5.8)	56	110.79
Autonomic nervous system imbalance								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Burning sensation								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Cervicobrachial syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic neuropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Disturbance in attention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	9	17.98	0			
Dizziness								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	3	3.21
>=8% (>=64 mmol/mol)	1	(1.0)	2	4.00	0			
Dizziness postural								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Encephalopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Haemorrhage intracranial								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Headache								
<8% (<64 mmol/mol)	12	(6.3)	17	18.43	7	(3.7)	8	8.55
>=8% (>=64 mmol/mol)	1	(1.0)	2	4.00	3	(2.9)	5	9.89
Hypoaesthesia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic seizure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hypoglycaemic unconsciousness								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hypotonia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Loss of consciousness								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Migraine								
<8% (<64 mmol/mol)	2	(1.1)	3	3.25	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post herpetic neuralgia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Sinus headache								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Somnolence								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Speech disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Syncope								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Tremor								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	48	94.96
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	5	(2.6)	5	5.42	4	(2.1)	5	5.34
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	3.96
Anxiety								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Attention deficit hyperactivity disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Depressed mood								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Depression								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Insomnia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Sleep disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	5	5.34
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	1	(1.0)	1	1.98
Chronic kidney disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Diabetic nephropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Hydrocalyx								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Hypertensive nephropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Renal cyst								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Renal pain								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	3	(1.6)	5	5.34
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Dysmenorrhoea								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Ectropion of cervix								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Fibrocystic breast disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Ovarian disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Penile pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Premenstrual syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Prostatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	12	(6.3)	13	14.09	12	(6.3)	13	13.89
>=8% (>=64 mmol/mol)	9	(8.9)	13	25.97	9	(8.7)	16	31.65
Allergic cough								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Bronchial hyperreactivity								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cough								
<8% (<64 mmol/mol)	1	(0.5)	2	2.17	3	(1.6)	3	3.21
>=8% (>=64 mmol/mol)	2	(2.0)	3	5.99	5	(4.9)	6	11.87
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Epistaxis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Hiccups								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Nasal congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Oropharyngeal pain								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	2	(1.9)	2	3.96
Pleurisy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Productive cough								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	3.96
Pulmonary congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Respiratory disorder								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Rhinitis allergic								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Rhinorrhoea								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	4	(3.9)	4	7.91
Sinus congestion								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	1	(1.0)	1	1.98
Sneezing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Throat irritation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	16	(8.5)	16	17.34	15	(7.9)	16	17.10
>=8% (>=64 mmol/mol)	8	(7.9)	8	15.98	9	(8.7)	16	31.65
Alopecia								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Angioedema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Blister								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Chronic spontaneous urticaria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				4	(3.9)	8	15.83
Dermal cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Dermatitis								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	0			
Dermatitis atopic								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				0			
Dermatitis contact								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	4	(2.1)	4	4.27
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	2	(1.9)	2	3.96
Dry skin								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Eczema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Erythema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Hidradenitis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Hyperkeratosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Ingrown hair								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			
Lichen sclerosus								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Macule								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Rash								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	0			
>=8% (>=64 mmol/mol)	0				0			
Rash erythematous								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Skin irritation								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Skin lesion								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Telangiectasia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			
Urticaria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	2.14
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	1.98
Xeroderma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	2.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	2.17	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac ablation								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Skin neoplasm excision								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Vascular disorders								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	4.34	1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	3	(2.9)	3	5.94
Arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.5)	1	1.08	0			
>=8% (>=64 mmol/mol)	0				0			
Hypertension								
<8% (<64 mmol/mol)	3	(1.6)	3	3.25	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	4.00	3	(2.9)	3	5.94
Varicose vein								
<8% (<64 mmol/mol)	0				1	(0.5)	1	1.07
>=8% (>=64 mmol/mol)	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.25 Adverse events by diabetes duration - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	211				230			
>=10 years	281				262			
PYE (years)								
<10 years	208.41				225.42			
>=10 years	277.47				259.61			
Events								
<10 years	146	(69.2)	480	230.32	155	(67.4)	527	233.78
>=10 years	205	(73.0)	747	269.22	180	(68.7)	635	244.60
Serious								
Yes								
<10 years	16	(7.6)	21	10.08	18	(7.8)	23	10.20
>=10 years	35	(12.5)	53	19.10	31	(11.8)	50	19.26
No								
<10 years	141	(66.8)	459	220.24	153	(66.5)	504	223.58
>=10 years	197	(70.1)	694	250.12	175	(66.8)	585	225.34
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	4	(1.9)	6	2.88	7	(3.0)	8	3.55
>=10 years	14	(5.0)	20	7.21	13	(5.0)	26	10.01
Moderate								
<10 years	58	(27.5)	98	47.02	63	(27.4)	123	54.56
>=10 years	94	(33.5)	182	65.59	73	(27.9)	128	49.30
Mild								
<10 years	124	(58.8)	376	180.42	126	(54.8)	396	175.67
>=10 years	168	(59.8)	545	196.42	160	(61.1)	481	185.28
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	10	(4.7)	17	8.16	13	(5.7)	23	10.20
>=10 years	9	(3.2)	10	3.60	16	(6.1)	22	8.47
Possible								
<10 years	14	(6.6)	19	9.12	12	(5.2)	19	8.43
>=10 years	20	(7.1)	27	9.73	19	(7.3)	27	10.40
Unlikely								
<10 years	144	(68.2)	443	212.56	151	(65.7)	485	215.15
>=10 years	199	(70.8)	710	255.88	174	(66.4)	585	225.34
Missing								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Related to technical complaint for basal insulin								
Yes								
<10 years	0				0			
>=10 years	0				0			
No								
<10 years	145	(68.7)	479	229.84	155	(67.4)	527	233.78
>=10 years	205	(73.0)	747	269.22	180	(68.7)	634	244.21
NA								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	3	(1.1)	4	1.44	2	(0.8)	3	1.16
Not recovered/not resolved								
<10 years	56	(26.5)	97	46.54	67	(29.1)	122	54.12
>=10 years	101	(35.9)	227	81.81	92	(35.1)	168	64.71
Recovered/resolved with sequelae								
<10 years	3	(1.4)	3	1.44	2	(0.9)	3	1.33
>=10 years	3	(1.1)	3	1.08	3	(1.1)	3	1.16
Recovering/resolving								
<10 years	7	(3.3)	12	5.76	9	(3.9)	9	3.99
>=10 years	12	(4.3)	14	5.05	11	(4.2)	12	4.62
Recovered/resolved								
<10 years	123	(58.3)	367	176.10	137	(59.6)	393	174.34
>=10 years	185	(65.8)	499	179.84	156	(59.5)	449	172.95
Unknown								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.26 Adverse events by diabetes duration - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	56				46			
>=10 years	206				217			
PYE (years)								
<10 years	33.44				26.89			
>=10 years	121.81				125.88			
Events								
<10 years	32	(57.1)	103	308.04	27	(58.7)	63	234.25
>=10 years	129	(62.6)	363	298.01	107	(49.3)	265	210.52
Serious								
Yes								
<10 years	5	(8.9)	10	29.91	0			
>=10 years	17	(8.3)	20	16.42	16	(7.4)	20	15.89
No								
<10 years	31	(55.4)	93	278.13	27	(58.7)	63	234.25
>=10 years	127	(61.7)	343	281.59	101	(46.5)	245	194.63
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	2	(3.6)	5	14.95	1	(2.2)	1	3.72
>=10 years	9	(4.4)	12	9.85	10	(4.6)	12	9.53
Moderate								
<10 years	17	(30.4)	44	131.59	12	(26.1)	18	66.93
>=10 years	47	(22.8)	78	64.03	42	(19.4)	64	50.84
Mild								
<10 years	24	(42.9)	54	161.50	22	(47.8)	44	163.61
>=10 years	108	(52.4)	273	224.12	87	(40.1)	189	150.15
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	1	(1.8)	1	2.99	1	(2.2)	3	11.15
>=10 years	8	(3.9)	8	6.57	5	(2.3)	10	7.94
Possible								
<10 years	3	(5.4)	3	8.97	0			
>=10 years	13	(6.3)	23	18.88	7	(3.2)	7	5.56
Unlikely								
<10 years	31	(55.4)	98	293.09	26	(56.5)	60	223.10
>=10 years	124	(60.2)	323	265.17	104	(47.9)	245	194.63
Missing								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	5	(2.4)	9	7.39	3	(1.4)	3	2.38
Related to technical complaint for basal insulin								
Yes								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
No								
<10 years	31	(55.4)	102	305.05	27	(58.7)	63	234.25
>=10 years	129	(62.6)	352	288.98	104	(47.9)	260	206.55
NA								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Missing								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	5	(2.4)	9	7.39	3	(1.4)	3	2.38

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	0				0			
>=10 years	2	(1.0)	3	2.46	2	(0.9)	2	1.59
Not recovered/not resolved								
<10 years	13	(23.2)	26	77.76	10	(21.7)	14	52.06
>=10 years	42	(20.4)	71	58.29	38	(17.5)	49	38.93
Recovered/resolved with sequelae								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Recovering/resolving								
<10 years	6	(10.7)	6	17.94	1	(2.2)	1	3.72
>=10 years	13	(6.3)	18	14.78	15	(6.9)	16	12.71
Recovered/resolved								
<10 years	29	(51.8)	71	212.34	20	(43.5)	48	178.48
>=10 years	106	(51.5)	271	222.48	80	(36.9)	197	156.50
Unknown								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.27 Adverse events by diabetes duration - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	56				61			
>=10 years	235				230			
PYE (years)								
<10 years	31.92				33.50			
>=10 years	135.44				133.30			
Events								
<10 years	25	(44.6)	58	181.69	34	(55.7)	120	358.23
>=10 years	146	(62.1)	397	293.12	133	(57.8)	430	322.58
Serious								
Yes								
<10 years	1	(1.8)	1	3.13	10	(16.4)	13	38.81
>=10 years	21	(8.9)	34	25.10	15	(6.5)	20	15.00
No								
<10 years	25	(44.6)	57	178.55	30	(49.2)	107	319.43
>=10 years	139	(59.1)	363	268.02	130	(56.5)	410	307.58
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	0				7	(11.5)	8	23.88
>=10 years	13	(5.5)	20	14.77	5	(2.2)	6	4.50
Moderate								
<10 years	9	(16.1)	14	43.86	13	(21.3)	23	68.66
>=10 years	50	(21.3)	85	62.76	48	(20.9)	98	73.52
Mild								
<10 years	22	(39.3)	44	137.83	29	(47.5)	89	265.69
>=10 years	116	(49.4)	292	215.60	119	(51.7)	326	244.56
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	3	(5.4)	6	18.80	1	(1.6)	1	2.99
>=10 years	6	(2.6)	7	5.17	6	(2.6)	7	5.25
Possible								
<10 years	3	(5.4)	3	9.40	2	(3.3)	2	5.97
>=10 years	20	(8.5)	31	22.89	15	(6.5)	41	30.76
Unlikely								
<10 years	22	(39.3)	49	153.49	33	(54.1)	117	349.28
>=10 years	135	(57.4)	359	265.06	129	(56.1)	382	286.57
Missing								
<10 years	0				0			
>=10 years	0				0			
Related to technical complaint for basal insulin								
Yes								
<10 years	0				1	(1.6)	1	2.99
>=10 years	5	(2.1)	5	3.69	2	(0.9)	3	2.25
No								
<10 years	25	(44.6)	58	181.69	34	(55.7)	119	355.25
>=10 years	145	(61.7)	392	289.43	133	(57.8)	426	319.58
NA								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	4	2.95	0			
Not recovered/not resolved								
<10 years	11	(19.6)	15	46.99	14	(23.0)	26	77.62
>=10 years	67	(28.5)	124	91.55	59	(25.7)	126	94.52
Recovered/resolved with sequelae								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				1	(0.4)	1	0.75
Recovering/resolving								
<10 years	1	(1.8)	4	12.53	3	(4.9)	5	14.93
>=10 years	15	(6.4)	28	20.67	13	(5.7)	17	12.75
Recovered/resolved								
<10 years	20	(35.7)	39	122.17	28	(45.9)	87	259.72
>=10 years	123	(52.3)	241	177.94	114	(49.6)	286	214.55
Unknown								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.28 Adverse events by diabetes duration - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	75				82			
>=10 years	215				210			
PYE (years)								
<10 years	37.23				40.36			
>=10 years	105.08				103.76			
Events								
<10 years	46	(61.3)	135	362.62	51	(62.2)	149	369.19
>=10 years	143	(66.5)	372	354.02	139	(66.2)	470	452.96
Serious								
Yes								
<10 years	4	(5.3)	4	10.74	2	(2.4)	2	4.96
>=10 years	7	(3.3)	11	10.47	5	(2.4)	7	6.75
No								
<10 years	42	(56.0)	131	351.87	50	(61.0)	147	364.23
>=10 years	143	(66.5)	361	343.55	137	(65.2)	463	446.21
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	5	(6.7)	5	13.43	0			
>=10 years	4	(1.9)	5	4.76	4	(1.9)	5	4.82
Moderate								
<10 years	12	(16.0)	22	59.09	11	(13.4)	16	39.64
>=10 years	39	(18.1)	68	64.71	40	(19.0)	73	70.35
Mild								
<10 years	39	(52.0)	108	290.09	48	(58.5)	133	329.55
>=10 years	130	(60.5)	299	284.55	122	(58.1)	392	377.79
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt ; variable(s): OTMTDURY DIABGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & ANELFL == "Y" & ANL06FL == "Y"
nn1436/nn1436-japan/submission_20221031_er
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Adverse events by diabetes duration - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	6	(8.0)	6	16.12	3	(3.7)	3	7.43
>=10 years	11	(5.1)	14	13.32	4	(1.9)	5	4.82
Possible								
<10 years	4	(5.3)	7	18.80	4	(4.9)	4	9.91
>=10 years	18	(8.4)	19	18.08	13	(6.2)	37	35.66
Unlikely								
<10 years	42	(56.0)	122	327.70	51	(62.2)	142	351.85
>=10 years	136	(63.3)	339	322.62	138	(65.7)	428	412.48
Missing								
<10 years	0				0			
>=10 years	0				0			
Related to technical complaint for basal insulin								
Yes								
<10 years	0				0			
>=10 years	0				0			
No								
<10 years	46	(61.3)	135	362.62	51	(62.2)	149	369.19
>=10 years	143	(66.5)	372	354.02	139	(66.2)	470	452.96
NA								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Not recovered/not resolved								
<10 years	20	(26.7)	25	67.15	19	(23.2)	39	96.63
>=10 years	66	(30.7)	109	103.73	64	(30.5)	105	101.19
Recovered/resolved with sequelae								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				2	(1.0)	2	1.93
Recovering/resolving								
<10 years	0				0			
>=10 years	6	(2.8)	6	5.71	5	(2.4)	8	7.71
Recovered/resolved								
<10 years	40	(53.3)	109	292.78	49	(59.8)	109	270.08
>=10 years	120	(55.8)	257	244.58	112	(53.3)	355	342.13
Unknown								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.29 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	211				230			
>=10 years	281				262			
PYE (years)								
<10 years	208.41				225.42			
>=10 years	277.47				259.61			
Events								
<10 years	146	(69.2)	480	230.32	155	(67.4)	527	233.78
>=10 years	205	(73.0)	747	269.22	180	(68.7)	635	244.60
Blood and lymphatic system disorders								
All								
<10 years	2	(0.9)	2	0.96	5	(2.2)	5	2.22
>=10 years	9	(3.2)	9	3.24	6	(2.3)	6	2.31
Anaemia								
<10 years	1	(0.5)	1	0.48	3	(1.3)	3	1.33
>=10 years	5	(1.8)	5	1.80	3	(1.1)	3	1.16
Blood loss anaemia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Eosinophilia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Hypochromic anaemia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Iron deficiency anaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Lymphadenopathy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Polycythaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Thrombocytopenia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	15	(7.1)	23	11.04	8	(3.5)	12	5.32
>=10 years	22	(7.8)	40	14.42	22	(8.4)	26	10.01
Acute coronary syndrome								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Acute myocardial infarction								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	4	(1.5)	4	1.54
Angina pectoris								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Angina unstable								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Aortic valve calcification								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Aortic valve incompetence								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Arrhythmia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Atrial fibrillation								
<10 years	3	(1.4)	3	1.44	2	(0.9)	2	0.89
>=10 years	5	(1.8)	6	2.16	2	(0.8)	2	0.77
Atrial flutter								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Atrial thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Atrioventricular block complete								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Bradycardia								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Bundle branch block right								
<10 years	0				2	(0.9)	3	1.33
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac dysfunction								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Cardiac failure								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	2	(0.7)	2	0.72	0			
Cardiac failure chronic								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Cardiac failure congestive								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Cardiac ventricular thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Chronic coronary syndrome								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Coronary artery disease								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	3	(1.1)	3	1.08	2	(0.8)	2	0.77
Coronary artery occlusion								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Diastolic dysfunction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Left atrial dilatation								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Left ventricular dysfunction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Left ventricular hypertrophy								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Mitral valve incompetence								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Myocardial infarction								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Palpitations								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Pericardial effusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Pericarditis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Sinus arrhythmia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Sinus bradycardia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Sinus tachycardia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Supraventricular extrasystoles								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Tachycardia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Tricuspid valve incompetence								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Ventricular extrasystoles								
<10 years	3	(1.4)	3	1.44	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Congenital syphilitic osteochondritis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Hydrocele								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Type V hyperlipidaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<10 years	4	(1.9)	4	1.92	3	(1.3)	3	1.33
>=10 years	4	(1.4)	4	1.44	6	(2.3)	7	2.70
Ear inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Ear pain								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Eustachian tube dysfunction								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Hypoacusis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Presbyacusis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Tinnitus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Vertigo								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	4	(1.5)	5	1.93
Vertigo positional								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<10 years	0				4	(1.7)	4	1.77
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Goitre								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Hyperplasia adrenal								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hyperprolactinaemia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hyperthyroidism								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Hypothyroidism								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Thyroid mass								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Eye disorders								
All								
<10 years	6	(2.8)	6	2.88	11	(4.8)	13	5.77
>=10 years	19	(6.8)	29	10.45	14	(5.3)	19	7.32
Acquired epiblepharon								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Asthenopia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Astigmatism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Blepharitis								
<10 years	0				0			
>=10 years	3	(1.1)	3	1.08	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	7	(2.5)	9	3.24	3	(1.1)	4	1.54
Conjunctival erosion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Conjunctival haemorrhage								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Conjunctivitis allergic								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.72	0			
Dacryoadenitis acquired								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Diabetic retinal oedema								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Diabetic retinopathy								
<10 years	1	(0.5)	1	0.48	3	(1.3)	3	1.33
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Diplopia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Dry eye								
<10 years	0				3	(1.3)	3	1.33
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Eye discharge								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Eye inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Eye pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Macular oedema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal tension glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Ocular hypertension								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Optic disc vascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Photophobia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Post thrombotic retinopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Posterior capsule opacification								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Retinal aneurysm								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Retinal artery occlusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Retinal detachment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Retinal tear								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Retinal vein occlusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Scintillating scotoma								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Uveitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Vision blurred								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Vitreous detachment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Vitreous haemorrhage								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Gastrointestinal disorders								
All								
<10 years	32	(15.2)	57	27.35	27	(11.7)	44	19.52
>=10 years	51	(18.1)	79	28.47	47	(17.9)	70	26.96
Abdominal discomfort								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Abdominal distension								
<10 years	3	(1.4)	3	1.44	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Abdominal pain								
<10 years	1	(0.5)	1	0.48	5	(2.2)	5	2.22
>=10 years	4	(1.4)	4	1.44	0			
Abdominal pain lower								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Abdominal pain upper								
<10 years	0				3	(1.3)	4	1.77
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Acid peptic disease								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.77
Anal fissure								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Anal pruritus								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Chronic gastritis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	2	(0.8)	2	0.77
Colitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(0.5)	1	0.48	2	(0.9)	2	0.89
>=10 years	0				0			
Colitis ischaemic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Colitis microscopic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Constipation								
<10 years	3	(1.4)	3	1.44	0			
>=10 years	1	(0.4)	1	0.36	5	(1.9)	5	1.93
Crohn's disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Dental caries								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	5	(1.8)	7	2.52	0			
Diarrhoea								
<10 years	9	(4.3)	12	5.76	8	(3.5)	8	3.55
>=10 years	22	(7.8)	31	11.17	13	(5.0)	14	5.39
Diverticulum								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Diverticulum intestinal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Dry mouth								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Duodenitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Dyspepsia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				2	(0.8)	2	0.77
Enteritis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Enterocolitis								
<10 years	2	(0.9)	3	1.44	0			
>=10 years	1	(0.4)	1	0.36	0			
Epigastric discomfort								
<10 years	0				1	(0.4)	1	0.44

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Flatulence								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Food poisoning								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Frequent bowel movements								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Gastric disorder								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Gastric polyps								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Gastrointestinal inflammation								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Gastrooesophageal reflux disease								
<10 years	1	(0.5)	1	0.48	3	(1.3)	3	1.33
>=10 years	5	(1.8)	5	1.80	3	(1.1)	3	1.16
Haematochezia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Haemorrhoids								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Hiatus hernia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Hyperaesthesia teeth								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Hyperchlorhydria								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Ileus								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Inguinal hernia								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Intra-abdominal haematoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Irritable bowel syndrome								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Large intestine polyp								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	3	1.16
Loose tooth								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Melaena								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Nausea								
<10 years	7	(3.3)	8	3.84	1	(0.4)	1	0.44
>=10 years	8	(2.8)	8	2.88	4	(1.5)	6	2.31
Oral discomfort								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Pancreatitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Pancreatitis acute								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Pancreatitis chronic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Periodontal disease								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Periodontal inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.77
Rectal polyp								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Rectal prolapse								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Stomatitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Tooth disorder								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Tooth impacted								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Toothache								
<10 years	6	(2.8)	6	2.88	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	1	(0.4)	1	0.39
Ulcerative gastritis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Umbilical hernia								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.77
Vomiting								
<10 years	3	(1.4)	3	1.44	3	(1.3)	4	1.77
>=10 years	1	(0.4)	1	0.36	5	(1.9)	7	2.70
General disorders and administration site conditions								
All								
<10 years	31	(14.7)	53	25.43	32	(13.9)	48	21.29
>=10 years	44	(15.7)	61	21.98	46	(17.6)	62	23.88
Asthenia								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	4	(1.5)	4	1.54
Chest discomfort								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Chest pain								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	1	(0.4)	1	0.39
Chills								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Death								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Discomfort								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Drug intolerance								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Early satiety								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Fatigue								
<10 years	6	(2.8)	7	3.36	1	(0.4)	1	0.44
>=10 years	7	(2.5)	7	2.52	4	(1.5)	4	1.54
Feeling abnormal								
<10 years	1	(0.5)	3	1.44	1	(0.4)	1	0.44
>=10 years	0				0			
Feeling hot								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Gait disturbance								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Hunger								
<10 years	3	(1.4)	4	1.92	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Implant site pruritus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Influenza like illness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Injection site bruising								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				0			
Injection site dermatitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Injection site erythema								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				4	(1.5)	4	1.54
Injection site haemorrhage								
<10 years	0				1	(0.4)	1	0.44

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Injection site hypersensitivity								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Injection site hypertrophy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Injection site mass								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Injection site pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Injection site reaction								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Injection site urticaria								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Malaise								
<10 years	3	(1.4)	4	1.92	2	(0.9)	3	1.33
>=10 years	2	(0.7)	2	0.72	6	(2.3)	7	2.70
Medical device site bruise								
<10 years	3	(1.4)	4	1.92	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Medical device site dermatitis								
<10 years	1	(0.5)	4	1.92	4	(1.7)	10	4.44
>=10 years	1	(0.4)	1	0.36	4	(1.5)	4	1.54
Medical device site eczema								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Medical device site erythema								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Medical device site haematoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Medical device site haemorrhage								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Medical device site hypersensitivity								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Medical device site pain								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Medical device site pruritus								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Medical device site reaction								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	3	1.08	0			
Non-cardiac chest pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Oedema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Oedema peripheral								
<10 years	0				2	(0.9)	2	0.89
>=10 years	5	(1.8)	5	1.80	3	(1.1)	4	1.54
Pain								
<10 years	0				2	(0.9)	2	0.89
>=10 years	3	(1.1)	3	1.08	4	(1.5)	4	1.54
Peripheral swelling								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	0				0			
Procedural failure								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Pyrexia								
<10 years	3	(1.4)	4	1.92	9	(3.9)	9	3.99
>=10 years	14	(5.0)	14	5.05	12	(4.6)	13	5.01
Swelling								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Thirst								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Vaccination site erythema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	3	1.08	2	(0.8)	2	0.77
Vaccination site reaction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<10 years	5	(2.4)	7	3.36	5	(2.2)	6	2.66
>=10 years	4	(1.4)	5	1.80	1	(0.4)	1	0.39
Cholelithiasis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Gallbladder cholesterolosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Hepatic cirrhosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hepatic cyst								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hepatic function abnormal								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hepatic steatosis								
<10 years	2	(0.9)	2	0.96	2	(0.9)	2	0.89
>=10 years	4	(1.4)	4	1.44	0			
Hypertransaminasaemia								
<10 years	1	(0.5)	2	0.96	0			
>=10 years	0				0			
Liver disorder								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Non-alcoholic steatohepatitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Nonalcoholic fatty liver disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Steatohepatitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<10 years	1	(0.5)	2	0.96	3	(1.3)	4	1.77
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Allergy to arthropod bite								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Immunisation reaction								
<10 years	0				1	(0.4)	2	0.89
>=10 years	0				0			
Seasonal allergy								
<10 years	1	(0.5)	1	0.48	2	(0.9)	2	0.89
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Infections and infestations								
All								
<10 years	72	(34.1)	116	55.66	89	(38.7)	140	62.11
>=10 years	97	(34.5)	147	52.98	104	(39.7)	147	56.62
Abscess								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Acarodermatitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Acute sinusitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Anal abscess								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Asymptomatic COVID-19								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Bacterial infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Balanitis candida								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Breast abscess								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Breast cellulitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Bronchitis								
<10 years	4	(1.9)	4	1.92	3	(1.3)	3	1.33
>=10 years	4	(1.4)	4	1.44	1	(0.4)	1	0.39
Candida infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Cellulitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Chlamydial infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Chronic hepatitis C								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Chronic sinusitis								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				1	(0.4)	1	0.39
Chronic tonsillitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Clostridium difficile infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Conjunctivitis								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Coronavirus infection								
<10 years	0				3	(1.3)	4	1.77
>=10 years	2	(0.7)	2	0.72	0			
COVID-19								
<10 years	26	(12.3)	26	12.48	25	(10.9)	25	11.09
>=10 years	23	(8.2)	23	8.29	36	(13.7)	37	14.25

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
<10 years	1	(0.5)	1	0.48	3	(1.3)	3	1.33
>=10 years	3	(1.1)	3	1.08	0			
Cystitis								
<10 years	1	(0.5)	1	0.48	4	(1.7)	5	2.22
>=10 years	4	(1.4)	5	1.80	4	(1.5)	4	1.54
Dermatophytosis of nail								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Diverticulitis								
<10 years	0				0			
>=10 years	0				4	(1.5)	4	1.54
Ear infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Empyema								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Endophthalmitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Epididymitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Erysipelas								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Escherichia urinary tract infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Eye infection bacterial								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Folliculitis								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Fungal balanitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Fungal infection								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
<10 years	1	(0.5)	2	0.96	1	(0.4)	1	0.44
>=10 years	0				0			
Gastroenteritis								
<10 years	3	(1.4)	3	1.44	4	(1.7)	4	1.77
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Gastroenteritis norovirus								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Gastroenteritis viral								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	0			
Gastrointestinal infection								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Genital infection fungal								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Giardiasis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Gingivitis								
<10 years	0				0			
>=10 years	2	(0.7)	3	1.08	1	(0.4)	1	0.39
Helicobacter gastritis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Helicobacter infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Herpes dermatitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Herpes simplex								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Herpes virus infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Herpes zoster								
<10 years	2	(0.9)	2	0.96	4	(1.7)	4	1.77
>=10 years	3	(1.1)	3	1.08	2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hordeolum								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Infected bite								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Influenza								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				1	(0.4)	1	0.39
Labyrinthitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Laryngitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Laryngopharyngitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Localised infection								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Lower respiratory tract infection								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	3	(1.1)	3	1.08	2	(0.8)	4	1.54
Lyme disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Mastitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Nail infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Nasopharyngitis								
<10 years	10	(4.7)	12	5.76	14	(6.1)	16	7.10
>=10 years	20	(7.1)	24	8.65	20	(7.6)	21	8.09
Onychomycosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Oophoritis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				0			
Oropharyngeal candidiasis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Osteomyelitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Otitis externa								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Otitis media								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Otitis media acute								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Otitis media chronic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Parotitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Peri-implantitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Pericoronitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Periodontitis								
<10 years	0				3	(1.3)	3	1.33
>=10 years	2	(0.7)	2	0.72	0			
Pharyngitis								
<10 years	5	(2.4)	5	2.40	6	(2.6)	8	3.55
>=10 years	6	(2.1)	8	2.88	3	(1.1)	3	1.16
Pharyngotonsillitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	2	0.77
Pneumonia								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post procedural infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Pulpitis dental								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Purulence								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Respiratory syncytial virus infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Respiratory tract infection								
<10 years	2	(0.9)	2	0.96	2	(0.9)	2	0.89
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Respiratory tract infection viral								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Rhinitis								
<10 years	3	(1.4)	3	1.44	3	(1.3)	3	1.33
>=10 years	3	(1.1)	3	1.08	1	(0.4)	1	0.39
Rotavirus infection								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Salpingitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Sepsis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Sinusitis								
<10 years	1	(0.5)	2	0.96	2	(0.9)	4	1.77
>=10 years	5	(1.8)	5	1.80	4	(1.5)	4	1.54
Skin bacterial infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Skin infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Subcutaneous abscess								
<10 years	0				1	(0.4)	2	0.89
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tinea infection								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Tonsillitis								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Tooth abscess								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Tooth infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Tracheitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Upper respiratory tract infection								
<10 years	12	(5.7)	17	8.16	4	(1.7)	5	2.22
>=10 years	11	(3.9)	13	4.69	9	(3.4)	9	3.47
Urethritis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Urinary tract infection								
<10 years	3	(1.4)	3	1.44	6	(2.6)	6	2.66
>=10 years	4	(1.4)	4	1.44	10	(3.8)	11	4.24
Vaginal infection								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Varicella								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Viral infection								
<10 years	1	(0.5)	1	0.48	4	(1.7)	4	1.77
>=10 years	2	(0.7)	2	0.72	0			
Viral pharyngitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Viral upper respiratory tract infection								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				2	(0.8)	2	0.77
Vulvovaginal candidiasis								
<10 years	2	(0.9)	3	1.44	2	(0.9)	2	0.89
>=10 years	0				2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal mycotic infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Injury, poisoning and procedural complications								
All								
<10 years	20	(9.5)	22	10.56	24	(10.4)	34	15.08
>=10 years	40	(14.2)	43	15.50	16	(6.1)	18	6.93
Accidental overdose								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Animal bite								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Ankle fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Arthropod sting								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Bone contusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Burn oral cavity								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Burns first degree								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Cervical vertebral fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Chillblains								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Contusion								
<10 years	0				3	(1.3)	3	1.33
>=10 years	5	(1.8)	6	2.16	2	(0.8)	2	0.77
Deafness traumatic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Endotracheal intubation complication								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Eye injury								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Fall								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	4	(1.4)	4	1.44	0			
Fibula fracture								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Foot fracture								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				0			
Hand fracture								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Heat illness								
<10 years	0				1	(0.4)	2	0.89
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Hip fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Injury								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Joint injury								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Ligament sprain								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Limb injury								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	0			
Lower limb fracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Meniscus injury								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Muscle strain								
<10 years	1	(0.5)	1	0.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.39
Overdose								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Post procedural fistula								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Post procedural haemorrhage								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Post procedural hypothyroidism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Post procedural stroke								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Post procedural swelling								
<10 years	0				1	(0.4)	2	0.89
>=10 years	0				0			
Procedural pain								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Radius fracture								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Rib fracture								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Scar								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Skin abrasion								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	1	(0.4)	1	0.36	0			
Skin laceration								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	0			
Soft tissue injury								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Thermal burn								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth fracture								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Traumatic haematoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Underdose								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Vaccination complication								
<10 years	3	(1.4)	3	1.44	8	(3.5)	12	5.32
>=10 years	7	(2.5)	7	2.52	5	(1.9)	7	2.70
Wound								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Wrist fracture								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Investigations								
All								
<10 years	8	(3.8)	8	3.84	15	(6.5)	16	7.10
>=10 years	13	(4.6)	16	5.77	6	(2.3)	6	2.31
Alanine aminotransferase increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Aspartate aminotransferase increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Blood cholesterol increased								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Blood creatine increased								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Blood creatine phosphokinase increased								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Blood glucose increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Blood pressure decreased								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Blood pressure increased								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Blood triglycerides increased								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Body temperature increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Cardiac stress test abnormal								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Electrocardiogram repolarisation abnormality								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Glycosylated haemoglobin increased								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Haemoglobin decreased								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hepatic enzyme increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
International normalised ratio abnormal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
International normalised ratio decreased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
International normalised ratio increased								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.72	0			
Lipids increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Red blood cell count decreased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
SARS-CoV-2 test positive								
<10 years	1	(0.5)	1	0.48	0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Transferrin saturation decreased								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Weight decreased								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	0			
Weight increased								
<10 years	1	(0.5)	1	0.48	9	(3.9)	9	3.99
>=10 years	4	(1.4)	4	1.44	1	(0.4)	1	0.39
Metabolism and nutrition disorders								
All								
<10 years	17	(8.1)	20	9.60	21	(9.1)	30	13.31
>=10 years	24	(8.5)	27	9.73	25	(9.5)	30	11.56
Appetite disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.77
Decreased appetite								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Dehydration								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Diabetes mellitus								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Dyslipidaemia								
<10 years	6	(2.8)	6	2.88	4	(1.7)	4	1.77
>=10 years	4	(1.4)	4	1.44	2	(0.8)	2	0.77
Electrolyte imbalance								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Fluid retention								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Gout								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	2	0.72	2	(0.8)	2	0.77
Hypercholesterolaemia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperglycaemia								
<10 years	0				4	(1.7)	4	1.77
>=10 years	0				2	(0.8)	2	0.77
Hyperkalaemia								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	3	(1.1)	4	1.44	2	(0.8)	2	0.77
Hyperlipidaemia								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Hypertriglyceridaemia								
<10 years	4	(1.9)	4	1.92	4	(1.7)	4	1.77
>=10 years	2	(0.7)	2	0.72	0			
Hyperuricaemia								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hypoglycaemia								
<10 years	1	(0.5)	2	0.96	5	(2.2)	13	5.77
>=10 years	3	(1.1)	3	1.08	4	(1.5)	7	2.70
Hypokalaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Increased appetite								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Iron deficiency								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Malnutrition								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Metabolic disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Obesity								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Vitamin D deficiency								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	3	(1.1)	3	1.08	3	(1.1)	3	1.16
Zinc deficiency								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders								
All								
<10 years	34	(16.1)	51	24.47	36	(15.7)	52	23.07
>=10 years	65	(23.1)	105	37.84	56	(21.4)	81	31.20
Arthralgia								
<10 years	9	(4.3)	11	5.28	5	(2.2)	5	2.22
>=10 years	14	(5.0)	16	5.77	12	(4.6)	14	5.39
Arthritis								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Axillary mass								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Back disorder								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Back pain								
<10 years	8	(3.8)	8	3.84	6	(2.6)	6	2.66
>=10 years	19	(6.8)	21	7.57	18	(6.9)	19	7.32
Bone cyst								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Bursitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Cervical spinal stenosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Chondropathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Coccydynia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Costochondritis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Dupuytren's contracture								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Exostosis								
<10 years	0				0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Fibromyalgia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Fistula								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Flank pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Groin pain								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Intervertebral disc disorder								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Intervertebral disc protrusion								
<10 years	1	(0.5)	1	0.48	2	(0.9)	3	1.33
>=10 years	3	(1.1)	4	1.44	1	(0.4)	1	0.39
Joint effusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Joint swelling								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Limb deformity								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Lumbar spinal stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Mastication disorder								
<10 years	0				1	(0.4)	2	0.89
>=10 years	0				0			
Muscle contracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Muscle spasms								
<10 years	1	(0.5)	1	0.48	3	(1.3)	3	1.33
>=10 years	7	(2.5)	7	2.52	1	(0.4)	1	0.39
Muscular weakness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal chest pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	0			
Musculoskeletal pain								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Musculoskeletal stiffness								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	0				0			
Myalgia								
<10 years	1	(0.5)	1	0.48	2	(0.9)	2	0.89
>=10 years	2	(0.7)	2	0.72	0			
Myositis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Neck pain								
<10 years	2	(0.9)	2	0.96	3	(1.3)	3	1.33
>=10 years	4	(1.4)	4	1.44	3	(1.1)	3	1.16
Osteoarthritis								
<10 years	3	(1.4)	4	1.92	2	(0.9)	2	0.89
>=10 years	9	(3.2)	10	3.60	7	(2.7)	8	3.08
Osteochondrosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Osteopenia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Pain in extremity								
<10 years	5	(2.4)	5	2.40	2	(0.9)	2	0.89
>=10 years	10	(3.6)	11	3.96	9	(3.4)	12	4.62
Periarthritis								
<10 years	2	(0.9)	2	0.96	3	(1.3)	3	1.33
>=10 years	4	(1.4)	4	1.44	1	(0.4)	1	0.39
Plantar fasciitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	3	1.08	1	(0.4)	1	0.39
Polyarthritis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Rotator cuff syndrome								
<10 years	0				0			
>=10 years	3	(1.1)	3	1.08	0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal osteoarthritis								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Spinal pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Spinal stenosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	0			
Synovial cyst								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Tendonitis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Tenosynovitis								
<10 years	1	(0.5)	1	0.48	3	(1.3)	4	1.77
>=10 years	0				2	(0.8)	2	0.77
Tenosynovitis stenosans								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Trigger finger								
<10 years	0				1	(0.4)	3	1.33
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Vertebral osteophyte								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	6	(2.8)	7	3.36	2	(0.9)	3	1.33
>=10 years	5	(1.8)	6	2.16	3	(1.1)	6	2.31
Acrochordon								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Basal cell carcinoma								
<10 years	0				2	(0.9)	2	0.89
>=10 years	1	(0.4)	1	0.36	0			
Colon cancer								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Dysplastic naevus								

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adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Glioblastoma multiforme								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Haemangioma of liver								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Hepatocellular carcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Malignant melanoma in situ								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Metastases to liver								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Neoplasm skin								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Oral fibroma								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Ovarian cancer metastatic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Pancreatic neoplasm								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Prostate cancer								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Renal cell carcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Salivary gland neoplasm								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Seborrhoeic keratosis								
<10 years	1	(0.5)	2	0.96	0			
>=10 years	1	(0.4)	1	0.36	0			
Uterine leiomyoma								
<10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.39
Nervous system disorders								
All								
<10 years	25	(11.8)	34	16.31	31	(13.5)	41	18.19
>=10 years	40	(14.2)	53	19.10	36	(13.7)	44	16.95
Ageusia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Anosmia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Balance disorder								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Brain injury								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Burning sensation								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Carotid arteriosclerosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Carpal tunnel syndrome								
<10 years	0				0			
>=10 years	4	(1.4)	4	1.44	2	(0.8)	2	0.77
Cerebral atrophy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Cerebral haemorrhage								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Cerebrovascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Cervical radiculopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Diabetic neuropathy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dizziness								
<10 years	6	(2.8)	8	3.84	6	(2.6)	6	2.66
>=10 years	6	(2.1)	8	2.88	8	(3.1)	9	3.47
Dizziness postural								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Dysgeusia								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Headache								
<10 years	9	(4.3)	11	5.28	10	(4.3)	15	6.65
>=10 years	7	(2.5)	7	2.52	7	(2.7)	9	3.47
Hypoaesthesia								
<10 years	1	(0.5)	1	0.48	3	(1.3)	4	1.77
>=10 years	4	(1.4)	6	2.16	0			
Lethargy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Lumbar radiculopathy								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				2	(0.8)	2	0.77
Memory impairment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Mental impairment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Migraine								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Neuralgia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Neuroglycopenia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	3	1.16
Neuropathy peripheral								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Paraesthesia								
<10 years	2	(0.9)	2	0.96	2	(0.9)	2	0.89
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Parkinsonian gait								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Post herpetic neuralgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Presyncope								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Sciatica								
<10 years	0				4	(1.7)	4	1.77
>=10 years	3	(1.1)	3	1.08	2	(0.8)	3	1.16
Somnolence								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Syncope								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	0			
Tension headache								
<10 years	0				0			
>=10 years	2	(0.7)	3	1.08	0			
Thrombotic stroke								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Transient ischaemic attack								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Tremor								
<10 years	3	(1.4)	3	1.44	0			
>=10 years	2	(0.7)	3	1.08	1	(0.4)	1	0.39
Trigeminal neuralgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Vertebral artery occlusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<10 years	6	(2.8)	6	2.88	3	(1.3)	3	1.33
>=10 years	9	(3.2)	10	3.60	7	(2.7)	7	2.70
Anxiety								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Bruxism								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Depressed mood								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Depression								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Insomnia								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	4	(1.4)	4	1.44	3	(1.1)	3	1.16
Mood swings								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Nightmare								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Persistent depressive disorder								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Sleep disorder								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	0			
Renal and urinary disorders								
All								
<10 years	3	(1.4)	5	2.40	5	(2.2)	5	2.22
>=10 years	11	(3.9)	13	4.69	15	(5.7)	17	6.55
Acute kidney injury								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Chronic kidney disease								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				2	(0.8)	2	0.77
Diabetic nephropathy								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Dysuria								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Haematuria								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				2	(0.8)	2	0.77
Microalbuminuria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Nephrolithiasis								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Nocturia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Pollakiuria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Pyelocaliectasis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Renal colic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Renal cyst								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Renal impairment								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Ureterolithiasis								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urinary incontinence								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Urinary retention								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Urinary tract obstruction								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Urine odour abnormal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Reproductive system and breast disorders								
All								
<10 years	1	(0.5)	1	0.48	2	(0.9)	3	1.33
>=10 years	9	(3.2)	9	3.24	5	(1.9)	6	2.31
Atrophic vulvovaginitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Benign prostatic hyperplasia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Breast mass								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Breast pain								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Erectile dysfunction								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	0			
Galactorrhoea								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Menopausal symptoms								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Ovarian cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Penile rash								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.77
Pruritus genital								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Uterine polyp								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Uterine prolapse								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Vulvovaginal dryness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Vulvovaginal pruritus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Respiratory, thoracic and mediastinal disorders								
All								
<10 years	19	(9.0)	28	13.44	21	(9.1)	24	10.65
>=10 years	26	(9.3)	31	11.17	17	(6.5)	28	10.79
Acquired diaphragmatic eventration								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Acute pulmonary oedema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Acute respiratory failure								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				1	(0.4)	1	0.39
Allergic bronchitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Asthma								
<10 years	1	(0.5)	2	0.96	0			
>=10 years	0				0			
Bronchiectasis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis chronic								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Chronic obstructive pulmonary disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Cough								
<10 years	4	(1.9)	4	1.92	6	(2.6)	6	2.66
>=10 years	6	(2.1)	6	2.16	2	(0.8)	3	1.16
Dyspnoea								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				4	(1.5)	4	1.54
Dyspnoea exertional								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Emphysema								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Epistaxis								
<10 years	0				1	(0.4)	2	0.89
>=10 years	0				0			
Haemoptysis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Interstitial lung disease								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	0				0			
Laryngeal cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Nasal congestion								
<10 years	2	(0.9)	2	0.96	2	(0.9)	2	0.89
>=10 years	3	(1.1)	3	1.08	0			
Nasal dryness								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Nasal turbinate hypertrophy								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Oropharyngeal pain								
<10 years	6	(2.8)	6	2.88	3	(1.3)	4	1.77
>=10 years	4	(1.4)	5	1.80	4	(1.5)	4	1.54

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paranasal sinus discomfort								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Pleural effusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Pleuritic pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Productive cough								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Pulmonary embolism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Pulmonary fibrosis								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.72	0			
Pulmonary mass								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Respiratory disorder								
<10 years	0				2	(0.9)	2	0.89
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Respiratory failure								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Rhinitis allergic								
<10 years	0				0			
>=10 years	0				1	(0.4)	5	1.93
Rhinorrhoea								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	2	(0.8)	2	0.77
Sinus congestion								
<10 years	1	(0.5)	2	0.96	0			
>=10 years	0				1	(0.4)	1	0.39
Sinus pain								
<10 years	1	(0.5)	2	0.96	0			
>=10 years	0				0			
Sleep apnoea syndrome								
<10 years	0				0			
>=10 years	3	(1.1)	3	1.08	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sneezing								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Throat irritation								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Upper-airway cough syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Skin and subcutaneous tissue disorders								
All								
<10 years	15	(7.1)	16	7.68	18	(7.8)	23	10.20
>=10 years	27	(9.6)	28	10.09	24	(9.2)	32	12.33
Actinic keratosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Alopecia								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	1	(0.4)	1	0.39
Alopecia areata								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Angioedema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Asteatosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Blister								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Cold sweat								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Cold urticaria								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Dermal cyst								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Dermatitis allergic								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Dermatitis contact								
<10 years	2	(0.9)	3	1.44	2	(0.9)	2	0.89
>=10 years	3	(1.1)	3	1.08	4	(1.5)	4	1.54
Diabetic foot								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Drug eruption								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Dry skin								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	2	(0.7)	2	0.72	0			
Ecchymosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Eczema								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	3	(1.1)	3	1.08	0			
Erythema								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Granuloma annulare								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Haemorrhage subcutaneous								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hyperhidrosis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Hyperkeratosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Ingrowing nail								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lentigo								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Lipodystrophy acquired								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Lipohypertrophy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Macule								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Miliaria								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				2	(0.8)	2	0.77
Myxoid cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Night sweats								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Pruritus								
<10 years	0				1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	2	(0.8)	2	0.77
Psoriasis								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	0				0			
Purpura								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Rash								
<10 years	1	(0.5)	1	0.48	2	(0.9)	2	0.89
>=10 years	1	(0.4)	1	0.36	4	(1.5)	4	1.54
Skin exfoliation								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				0			
Skin fissures								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Skin irritation								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	1	(0.4)	2	0.72	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin lesion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Skin ulcer								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Urticaria								
<10 years	0				2	(0.9)	2	0.89
>=10 years	0				2	(0.8)	2	0.77
Urticaria contact								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Urticaria thermal								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Surgical and medical procedures								
All								
<10 years	1	(0.5)	1	0.48	1	(0.4)	1	0.44
>=10 years	0				1	(0.4)	1	0.39
Knee operation								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Large intestinal polypectomy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Removal of foreign body								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Vascular disorders								
All								
<10 years	11	(5.2)	11	5.28	13	(5.7)	13	5.77
>=10 years	21	(7.5)	26	9.37	12	(4.6)	16	6.16
Aortic arteriosclerosis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	2	(0.7)	2	0.72	0			
Aortic stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	2	(0.8)	2	0.77
Blood pressure inadequately controlled								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Brachiocephalic arteriosclerosis								
<10 years	0				2	(0.9)	2	0.89
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Flushing								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Haematoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Hypertension								
<10 years	5	(2.4)	5	2.40	5	(2.2)	5	2.22
>=10 years	8	(2.8)	8	2.88	5	(1.9)	6	2.31
Hypertensive crisis								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Hypertensive urgency								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Hypotension								
<10 years	2	(0.9)	2	0.96	1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Iliac artery stenosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Intermittent claudication								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.39
Macroangiopathy								
<10 years	0				1	(0.4)	1	0.44
>=10 years	0				0			
Peripheral arterial occlusive disease								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	2	0.72	1	(0.4)	1	0.39
Peripheral artery occlusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.72	0			
Peripheral coldness								
<10 years	2	(0.9)	2	0.96	0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39
Peripheral vascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Peripheral venous disease								
<10 years	0				1	(0.4)	1	0.44
>=10 years	1	(0.4)	1	0.36	0			
Superficial vein thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	0			
Thrombosis								
<10 years	1	(0.5)	1	0.48	0			
>=10 years	0				0			
Varicose vein								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.36	1	(0.4)	1	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.30 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	56				46			
>=10 years	206				217			
PYE (years)								
<10 years	33.44				26.89			
>=10 years	121.81				125.88			
Events								
<10 years	32	(57.1)	103	308.04	27	(58.7)	63	234.25
>=10 years	129	(62.6)	363	298.01	107	(49.3)	265	210.52
Blood and lymphatic system disorders								
All								
<10 years	1	(1.8)	3	8.97	1	(2.2)	1	3.72
>=10 years	0				0			
Anaemia								
<10 years	1	(1.8)	3	8.97	0			
>=10 years	0				0			
Thrombocytosis								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
<10 years	0				1	(2.2)	1	3.72
>=10 years	5	(2.4)	7	5.75	1	(0.5)	1	0.79
Acute myocardial infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Atrial fibrillation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Bradycardia								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Cardiac failure congestive								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Cardiac flutter								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Coronary artery disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Myocardial infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Supraventricular tachycardia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<10 years	2	(3.6)	2	5.98	0			
>=10 years	2	(1.0)	2	1.64	4	(1.8)	4	3.18
Deafness unilateral								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Ear pain								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				1	(0.5)	1	0.79
Hypoacusis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Tinnitus								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Vertigo								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Endocrine disorders								
All								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	2.38
Adrenocortical insufficiency acute								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Hypothyroidism								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Inappropriate antidiuretic hormone secretion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Eye disorders								
All								
<10 years	6	(10.7)	8	23.93	3	(6.5)	3	11.15
>=10 years	21	(10.2)	23	18.88	22	(10.1)	27	21.45
Astigmatism								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	4	(1.8)	4	3.18
Cataract nuclear								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Conjunctival haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Diabetic retinal oedema								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Diabetic retinopathy								
<10 years	3	(5.4)	4	11.96	3	(6.5)	3	11.15
>=10 years	7	(3.4)	7	5.75	13	(6.0)	14	11.12
Dry age-related macular degeneration								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Dry eye								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Epiretinal membrane								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Eye irritation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Lacrimation increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Macular oedema								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Myopia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Non-proliferative retinopathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ocular hyperaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Ocular hypertension								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Presbyopia								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.59
Retinal exudates								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Retinal haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Retinal vein occlusion								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Vision blurred								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Visual acuity reduced								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Vitreous haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Gastrointestinal disorders								
All								
<10 years	6	(10.7)	9	26.92	7	(15.2)	9	33.46
>=10 years	32	(15.5)	51	41.87	25	(11.5)	33	26.22
Abdominal pain								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			
Abdominal pain lower								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Abdominal pain upper								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	3	2.46	2	(0.9)	2	1.59
Chronic gastritis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Constipation								
<10 years	0				0			
>=10 years	4	(1.9)	7	5.75	0			
Dental caries								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.59
Diarrhoea								
<10 years	2	(3.6)	2	5.98	2	(4.3)	2	7.44
>=10 years	12	(5.8)	15	12.31	7	(3.2)	7	5.56
Diverticulum								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Dyspepsia								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Flatulence								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Food poisoning								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	2	1.59
Gastric dysplasia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Gastric mucosal hypertrophy								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Gastric polyps								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Gastritis								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Gastrointestinal angiodysplasia								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Gastrooesophageal reflux disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Gingival bleeding								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Haemorrhoids								
<10 years	1	(1.8)	1	2.99	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				2	(0.9)	2	1.59
Hiatus hernia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Hyperaesthesia teeth								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Intra-abdominal haematoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Large intestine polyp								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Nausea								
<10 years	0				2	(4.3)	2	7.44
>=10 years	7	(3.4)	7	5.75	4	(1.8)	4	3.18
Pancreatic pseudocyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Periodontal disease								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Tongue rough								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Toothache								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	3	(1.4)	5	3.97
Vomiting								
<10 years	0				1	(2.2)	1	3.72
>=10 years	3	(1.5)	3	2.46	2	(0.9)	2	1.59
General disorders and administration site conditions								
All								
<10 years	7	(12.5)	7	20.93	4	(8.7)	4	14.87
>=10 years	18	(8.7)	29	23.81	15	(6.9)	17	13.51
Asthenia								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	0				0			
Chest discomfort								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			
Chest pain								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Chills								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Condition aggravated								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Fatigue								
<10 years	0				0			
>=10 years	2	(1.0)	3	2.46	3	(1.4)	3	2.38
Hunger								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Influenza like illness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Injection site reaction								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Injection site swelling								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Malaise								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	2	(0.9)	3	2.38
Medical device site bruise								
<10 years	0				0			
>=10 years	1	(0.5)	2	1.64	0			
Medical device site dermatitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Medical device site erythema								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Medical device site pruritus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Medical device site rash								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Medical device site reaction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oedema peripheral								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			
Pain								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Pyrexia								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	5	(2.4)	5	4.10	5	(2.3)	5	3.97
Vaccination site pain								
<10 years	0				0			
>=10 years	3	(1.5)	4	3.28	3	(1.4)	3	2.38
Hepatobiliary disorders								
All								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Alcoholic liver disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Gallbladder polyp								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Hepatic cirrhosis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Immune system disorders								
All								
<10 years	1	(1.8)	1	2.99	2	(4.3)	2	7.44
>=10 years	1	(0.5)	1	0.82	3	(1.4)	3	2.38
Allergy to arthropod bite								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Allergy to arthropod sting								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Anaphylactic reaction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Seasonal allergy								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	0				1	(0.5)	1	0.79

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infections and infestations								
All								
<10 years	19	(33.9)	32	95.70	8	(17.4)	12	44.62
>=10 years	57	(27.7)	66	54.18	41	(18.9)	54	42.90
Abscess limb								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				1	(0.5)	1	0.79
Anal abscess								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Bronchitis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			
Campylobacter gastroenteritis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Cellulitis								
<10 years	0				1	(2.2)	2	7.44
>=10 years	1	(0.5)	1	0.82	0			
Conjunctivitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
COVID-19								
<10 years	2	(3.6)	2	5.98	1	(2.2)	1	3.72
>=10 years	7	(3.4)	7	5.75	6	(2.8)	6	4.77
COVID-19 pneumonia								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Cystitis								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	1	(0.5)	2	1.59
Ear infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Enteritis infectious								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Eye infection								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Folliculitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Fungal infection								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	1	(0.5)	2	1.64	0			
Fungal skin infection								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Gastroenteritis								
<10 years	0				1	(2.2)	1	3.72
>=10 years	5	(2.4)	5	4.10	1	(0.5)	1	0.79
Gastrointestinal infection								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Gingivitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Helicobacter infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Herpes zoster								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	2.38
Influenza								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	4	(1.8)	5	3.97
Kidney infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Localised infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Nasopharyngitis								
<10 years	9	(16.1)	14	41.87	1	(2.2)	1	3.72
>=10 years	13	(6.3)	14	11.49	9	(4.1)	13	10.33
Onychomycosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Otitis media								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Paraspinal abscess								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Peritonsillar abscess								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumonia								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Pulpitis dental								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				1	(0.5)	1	0.79
Pustule								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Rhinitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	3	2.38
Sinusitis								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	3	(1.4)	3	2.38
Soft tissue infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Subcutaneous abscess								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Tinea pedis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Tinea versicolour								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Tonsillitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Tooth abscess								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Tooth infection								
<10 years	1	(1.8)	2	5.98	2	(4.3)	2	7.44
>=10 years	0				1	(0.5)	1	0.79
Upper respiratory tract infection								
<10 years	0				2	(4.3)	2	7.44
>=10 years	8	(3.9)	11	9.03	2	(0.9)	2	1.59
Urinary tract infection								
<10 years	2	(3.6)	2	5.98	1	(2.2)	1	3.72
>=10 years	2	(1.0)	3	2.46	2	(0.9)	2	1.59
Vaginal infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella zoster virus infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Vulvitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Vulvovaginal candidiasis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Wound infection								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Injury, poisoning and procedural complications								
All								
<10 years	6	(10.7)	6	17.94	5	(10.9)	5	18.59
>=10 years	21	(10.2)	33	27.09	17	(7.8)	21	16.68
Accidental overdose								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	3	(1.5)	3	2.46	0			
Arthropod bite								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Arthropod sting								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Bone contusion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Contusion								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	0			
Craniocerebral injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Face injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Facial bones fracture								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Fall								
<10 years	1	(1.8)	1	2.99	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	4	(1.9)	4	3.28	2	(0.9)	2	1.59
Foot fracture								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Hand fracture								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Heat illness								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Intentional overdose								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Joint injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Ligament sprain								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Limb injury								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.59
Muscle contusion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Muscle injury								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Overdose								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Rib fracture								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Road traffic accident								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Skin abrasion								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Skin laceration								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Stab wound								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Subcutaneous haematoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Tendon injury								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Tendon rupture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Thermal burn								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Tibia fracture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Underdose								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Vaccination complication								
<10 years	0				0			
>=10 years	4	(1.9)	8	6.57	3	(1.4)	3	2.38
Wound								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Wrist fracture								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
<10 years	2	(3.6)	2	5.98	0			
>=10 years	3	(1.5)	3	2.46	3	(1.4)	4	3.18
Alanine aminotransferase increased								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Blood creatinine increased								
<10 years	0				0			
>=10 years	3	(1.5)	3	2.46	0			
Blood potassium increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Intraocular pressure increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Liver function test abnormal								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.59
SARS-CoV-2 test positive								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<10 years	1	(1.8)	1	2.99	4	(8.7)	4	14.87
>=10 years	6	(2.9)	6	4.93	7	(3.2)	12	9.53
Abnormal weight gain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Hyperammonaemia								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Hypercholesterolaemia								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Hyperglycaemia								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	2	(0.9)	2	1.59
Hyperkalaemia								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Hyperlipidaemia								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Hyperuricaemia								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Hypoglycaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	3	(1.4)	8	6.36
Musculoskeletal and connective tissue disorders								
All								
<10 years	9	(16.1)	11	32.90	6	(13.0)	10	37.18
>=10 years	29	(14.1)	49	40.23	23	(10.6)	35	27.80
Arthralgia								
<10 years	1	(1.8)	1	2.99	4	(8.7)	5	18.59
>=10 years	5	(2.4)	6	4.93	6	(2.8)	8	6.36
Arthritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Axillary mass								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Back pain								
<10 years	4	(7.1)	4	11.96	1	(2.2)	2	7.44
>=10 years	3	(1.5)	3	2.46	10	(4.6)	11	8.74
Bursitis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Flank pain								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Intervertebral disc disorder								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Intervertebral disc protrusion								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Muscle spasms								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	8	(3.9)	10	8.21	1	(0.5)	1	0.79
Musculoskeletal stiffness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Myalgia								
<10 years	0				0			
>=10 years	4	(1.9)	4	3.28	2	(0.9)	2	1.59
Neck pain								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Osteoarthritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Osteoporosis								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Pain in extremity								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	2	(1.0)	2	1.64	4	(1.8)	5	3.97
Periarthritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Plantar fasciitis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Polymyalgia rheumatica								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	3	2.38
Rheumatoid arthritis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Rotator cuff syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Soft tissue swelling								
<10 years	0				0			
>=10 years	1	(0.5)	3	2.46	0			
Spinal stenosis								
<10 years	0				0			
>=10 years	2	(1.0)	4	3.28	0			
Tendonitis								
<10 years	0				0			
>=10 years	2	(1.0)	4	3.28	0			
Tenosynovitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Trigger finger								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	2	(1.0)	2	1.64	4	(1.8)	4	3.18
Breast cancer								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Chronic myeloid leukaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Colon adenoma								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Colon cancer stage II								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Gastric cancer								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Lymphangioma								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Pancreatic carcinoma metastatic								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Nervous system disorders								
All								
<10 years	7	(12.5)	9	26.92	5	(10.9)	9	33.46
>=10 years	20	(9.7)	33	27.09	20	(9.2)	25	19.86
Autonomic nervous system imbalance								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Burning sensation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Carotid artery aneurysm								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Carpal tunnel syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cerebral infarction								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Cervicobrachial syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Diabetic neuropathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Dizziness								
<10 years	1	(1.8)	1	2.99	2	(4.3)	5	18.59
>=10 years	3	(1.5)	4	3.28	7	(3.2)	8	6.36
Facial paralysis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Headache								
<10 years	4	(7.1)	5	14.95	2	(4.3)	2	7.44
>=10 years	10	(4.9)	15	12.31	7	(3.2)	8	6.36
Hypoaesthesia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Migraine								
<10 years	2	(3.6)	2	5.98	0			
>=10 years	0				0			
Neuralgia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Neuropathy peripheral								
<10 years	0				1	(2.2)	1	3.72
>=10 years	0				0			
Peripheral paralysis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Piriformis syndrome								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Post herpetic neuralgia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Restless legs syndrome								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sciatica								
<10 years	0				1	(2.2)	1	3.72
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Somnolence								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Syncope								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Tension headache								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Thalamic infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Thrombotic stroke								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Tremor								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.59
Psychiatric disorders								
All								
<10 years	0				0			
>=10 years	4	(1.9)	5	4.10	5	(2.3)	5	3.97
Adjustment disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Depression								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	2	(0.9)	2	1.59
Insomnia								
<10 years	0				0			
>=10 years	3	(1.5)	3	2.46	0			
Major depression								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Sleep disorder								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.59

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<10 years	2	(3.6)	4	11.96	0			
>=10 years	6	(2.9)	6	4.93	0			
Bladder prolapse								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Diabetic nephropathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Hydronephrosis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Nephrotic syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Pollakiuria								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Polyuria								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Renal cyst								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Renal impairment								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Urethral stenosis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Urine odour abnormal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<10 years	1	(1.8)	1	2.99	1	(2.2)	1	3.72
>=10 years	3	(1.5)	3	2.46	1	(0.5)	1	0.79
Benign prostatic hyperplasia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Cervical polyp								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Erectile dysfunction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Prostatitis								
<10 years	0				1	(2.2)	1	3.72
>=10 years	1	(0.5)	1	0.82	0			
Pruritus genital								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Respiratory, thoracic and mediastinal disorders								
All								
<10 years	2	(3.6)	2	5.98	0			
>=10 years	13	(6.3)	27	22.17	4	(1.8)	5	3.97
Acute respiratory failure								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Chronic obstructive pulmonary disease								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Cough								
<10 years	0				0			
>=10 years	2	(1.0)	3	2.46	0			
Epistaxis								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	2	(1.0)	6	4.93	0			
Nasal congestion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Nasal obstruction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal septum deviation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Oropharyngeal pain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	2	(0.9)	3	2.38
Productive cough								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Respiratory failure								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Rhinorrhoea								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	4	(1.9)	6	4.93	1	(0.5)	1	0.79
Sleep apnoea syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Sneezing								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
<10 years	4	(7.1)	4	11.96	0			
>=10 years	9	(4.4)	10	8.21	6	(2.8)	6	4.77
Alopecia								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Blister								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				0			
Dermal cyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Dermatitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Eczema								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	0				1	(0.5)	1	0.79
Hyperhidrosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	1	(0.5)	1	0.79
Miliaria								
<10 years	0				0			
>=10 years	2	(1.0)	2	1.64	0			
Neurodermatitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Pruritus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Rash								
<10 years	1	(1.8)	1	2.99	0			
>=10 years	2	(1.0)	2	1.64	1	(0.5)	1	0.79
Rash papular								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			
Urticaria								
<10 years	0				0			
>=10 years	3	(1.5)	3	2.46	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Toe amputation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.79
Vascular disorders								
All								
<10 years	0				2	(4.3)	2	7.44
>=10 years	5	(2.4)	5	4.10	3	(1.4)	3	2.38
Hypertension								
<10 years	0				2	(4.3)	2	7.44
>=10 years	4	(1.9)	4	3.28	3	(1.4)	3	2.38
Orthostatic hypotension								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.82	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.31 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	56				61			
>=10 years	235				230			
PYE (years)								
<10 years	31.92				33.50			
>=10 years	135.44				133.30			
Events								
<10 years	25	(44.6)	58	181.69	34	(55.7)	120	358.23
>=10 years	146	(62.1)	397	293.12	133	(57.8)	430	322.58
Blood and lymphatic system disorders								
All								
<10 years	1	(1.8)	1	3.13	1	(1.6)	1	2.99
>=10 years	6	(2.6)	6	4.43	4	(1.7)	4	3.00
Anaemia								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	2	(0.9)	2	1.48	3	(1.3)	3	2.25
Blood loss anaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Eosinophilia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Iron deficiency anaemia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Lymphadenopathy mediastinal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Cardiac disorders								
All								
<10 years	0				4	(6.6)	6	17.91
>=10 years	7	(3.0)	8	5.91	10	(4.3)	16	12.00
Acute myocardial infarction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Angina pectoris								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Aortic valve calcification								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Aortic valve sclerosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Atrial enlargement								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Atrial fibrillation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Bundle branch block left								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Bundle branch block right								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Cardiac failure								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	1.50
Cardiac failure congestive								
<10 years	0				2	(3.3)	3	8.96
>=10 years	0				0			
Cardiac perfusion defect								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	1.50
Coronary artery disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Left atrial enlargement								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Left ventricular hypertrophy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Myocardial infarction								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Myocardial ischaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Palpitations								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Pericarditis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Sinus bradycardia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Tachycardia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Congenital, familial and genetic disorders								
All								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Corneal dystrophy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Ear and labyrinth disorders								
All								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	4	(1.7)	4	3.00
Cerumen impaction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Ear discomfort								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Middle ear inflammation								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Vertigo								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	0			
Adrenocortical insufficiency acute								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Hypogonadism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hypothyroidism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Eye disorders								
All								
<10 years	3	(5.4)	3	9.40	6	(9.8)	6	17.91
>=10 years	23	(9.8)	30	22.15	32	(13.9)	51	38.26
Age-related macular degeneration								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Astigmatism								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Cataract								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	4	(1.7)	6	4.50
Corneal erosion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Diabetic retinal oedema								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	1	(0.4)	1	0.74	3	(1.3)	4	3.00
Diabetic retinopathy								
<10 years	1	(1.8)	1	3.13	2	(3.3)	2	5.97
>=10 years	11	(4.7)	13	9.60	13	(5.7)	13	9.75
Diplopia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Eye discharge								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye inflammation								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				1	(0.4)	1	0.75
Eye pain								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Macular degeneration								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Macular oedema								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Meibomianitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Open angle glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	1.50
Presbyopia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Retinal deposits								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Retinal detachment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Retinal drusen								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Retinal exudates								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Retinal haemorrhage								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Retinal scar								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Retinal vascular disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Retinopathy hypertensive								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	4	(1.7)	4	3.00

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Visual impairment								
<10 years	0				0			
>=10 years	0				1	(0.4)	9	6.75
Vitreous detachment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Vitreous haemorrhage								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Gastrointestinal disorders								
All								
<10 years	5	(8.9)	8	25.06	11	(18.0)	15	44.78
>=10 years	30	(12.8)	42	31.01	24	(10.4)	34	25.51
Abdominal discomfort								
<10 years	0				1	(1.6)	2	5.97
>=10 years	1	(0.4)	1	0.74	0			
Abdominal distension								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Abdominal pain								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	5	(2.2)	6	4.50
Abdominal pain upper								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Chronic gastritis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	0			
Constipation								
<10 years	2	(3.6)	2	6.27	2	(3.3)	2	5.97
>=10 years	0				1	(0.4)	1	0.75
Dental caries								
<10 years	0				0			
>=10 years	0				4	(1.7)	4	3.00
Diarrhoea								
<10 years	0				3	(4.9)	3	8.96
>=10 years	15	(6.4)	18	13.29	6	(2.6)	6	4.50
Eructation								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Faeces pale								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Food poisoning								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Gastrointestinal disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Gastrointestinal haemorrhage								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Gastrooesophageal reflux disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Gingival disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Hypoaesthesia oral								
<10 years	0				0			
>=10 years	2	(0.9)	4	2.95	0			
Nausea								
<10 years	2	(3.6)	2	6.27	0			
>=10 years	3	(1.3)	3	2.22	4	(1.7)	4	3.00
Pancreatic duct dilatation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pancreatic failure								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pancreatitis chronic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Periodontal disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Proctalgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Toothache								
<10 years	0				2	(3.3)	3	8.96
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Upper gastrointestinal haemorrhage								
<10 years	0				1	(1.6)	1	2.99

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Vomiting								
<10 years	2	(3.6)	4	12.53	0			
>=10 years	5	(2.1)	5	3.69	2	(0.9)	2	1.50
General disorders and administration site conditions								
All								
<10 years	4	(7.1)	5	15.66	8	(13.1)	10	29.85
>=10 years	22	(9.4)	33	24.37	18	(7.8)	26	19.50
Asthenia								
<10 years	1	(1.8)	1	3.13	1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Axillary pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Chest pain								
<10 years	0				0			
>=10 years	3	(1.3)	3	2.22	0			
Cyst								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Discomfort								
<10 years	0				0			
>=10 years	0				1	(0.4)	8	6.00
Facial pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Fatigue								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	3	(1.3)	4	2.95	1	(0.4)	1	0.75
Feeling abnormal								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Injection site pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Injection site rash								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Injection site reaction								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Malaise								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	2	1.50
Medical device site dermatitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Medical device site erythema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Medical device site pain								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Medical device site reaction								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Multiple organ dysfunction syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Oedema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Oedema due to renal disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Oedema peripheral								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Pain								
<10 years	1	(1.8)	1	3.13	1	(1.6)	1	2.99
>=10 years	2	(0.9)	3	2.22	0			
Peripheral swelling								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Pyrexia								
<10 years	0				3	(4.9)	4	11.94
>=10 years	3	(1.3)	3	2.22	3	(1.3)	3	2.25
Thirst								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Vaccination site inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
<10 years	0				1	(1.6)	1	2.99
>=10 years	3	(1.3)	3	2.22	1	(0.4)	1	0.75
Vaccination site pruritus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Xerosis								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Hepatobiliary disorders								
All								
<10 years	0				2	(3.3)	4	11.94
>=10 years	2	(0.9)	3	2.22	2	(0.9)	2	1.50
Biliary dyskinesia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Cholecystitis chronic								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Gallbladder polyp								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Hepatic function abnormal								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Hepatic steatosis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Hepatomegaly								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hyperplastic cholecystopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Liver disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<10 years	0				0			
>=10 years	3	(1.3)	3	2.22	2	(0.9)	2	1.50
Drug hypersensitivity								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hypersensitivity								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Seasonal allergy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Infections and infestations								
All								
<10 years	12	(21.4)	16	50.12	15	(24.6)	27	80.60
>=10 years	75	(31.9)	101	74.57	64	(27.8)	93	69.77
Abscess								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Asymptomatic COVID-19								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Bacteraemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Breast abscess								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Bronchitis								
<10 years	2	(3.6)	2	6.27	0			
>=10 years	6	(2.6)	6	4.43	3	(1.3)	3	2.25
Candida infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Cellulitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Cholecystitis infective								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctivitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Coronavirus infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	1.50
COVID-19								
<10 years	4	(7.1)	4	12.53	5	(8.2)	6	17.91
>=10 years	22	(9.4)	22	16.24	18	(7.8)	19	14.25
COVID-19 pneumonia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	4	(1.7)	4	2.95	0			
Cystitis								
<10 years	0				2	(3.3)	2	5.97
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Diabetic foot infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Eye infection								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Fungal infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Fungal skin infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Gastroenteritis								
<10 years	3	(5.4)	3	9.40	1	(1.6)	1	2.99
>=10 years	4	(1.7)	4	2.95	4	(1.7)	5	3.75
Gastroenteritis viral								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Gingivitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Herpes zoster								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Infected dermal cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Influenza								
<10 years	2	(3.6)	2	6.27	3	(4.9)	4	11.94
>=10 years	3	(1.3)	3	2.22	5	(2.2)	6	4.50

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Localised infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Nasopharyngitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	8	(3.4)	8	5.91	11	(4.8)	14	10.50
Oral herpes								
<10 years	0				0			
>=10 years	1	(0.4)	2	1.48	0			
Osteomyelitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Otitis media								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Otitis media acute								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Paronychia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	2	1.50
Periodontitis								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Pharyngitis								
<10 years	2	(3.6)	2	6.27	1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	5	(2.2)	5	3.75
Pharyngotonsillitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pneumonia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	3	(1.3)	3	2.22	0			
Pneumonia viral								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Post procedural infection								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulmonary tuberculoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pulpitis dental								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Respiratory syncytial virus infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Respiratory tract infection								
<10 years	0				1	(1.6)	1	2.99
>=10 years	3	(1.3)	3	2.22	1	(0.4)	1	0.75
Respiratory tract infection viral								
<10 years	1	(1.8)	2	6.27	1	(1.6)	1	2.99
>=10 years	5	(2.1)	5	3.69	4	(1.7)	5	3.75
Sepsis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Sinusitis								
<10 years	0				0			
>=10 years	3	(1.3)	4	2.95	2	(0.9)	2	1.50
Soft tissue infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Tooth abscess								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	2	(0.9)	3	2.25
Tooth infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Upper respiratory tract infection								
<10 years	0				0			
>=10 years	6	(2.6)	6	4.43	6	(2.6)	6	4.50
Urinary tract infection								
<10 years	0				1	(1.6)	2	5.97
>=10 years	3	(1.3)	3	2.22	4	(1.7)	5	3.75
Viral infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Viral rhinitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral tracheitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Vulvovaginal mycotic infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Injury, poisoning and procedural complications								
All								
<10 years	0				6	(9.8)	8	23.88
>=10 years	19	(8.1)	25	18.46	21	(9.1)	27	20.25
Accidental overdose								
<10 years	0				1	(1.6)	2	5.97
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Accidental underdose								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Animal bite								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Arthropod bite								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Arthropod sting								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Chillblains								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Concussion								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Contusion								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Crush injury								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Exposure to SARS-CoV-2								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Extra dose administered								
<10 years	0				0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.74	0			
Fall								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Foot fracture								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Incorrect dose administered								
<10 years	0				0			
>=10 years	3	(1.3)	3	2.22	1	(0.4)	2	1.50
Joint injury								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Ligament sprain								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				1	(0.4)	1	0.75
Limb injury								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Medication error								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Meniscus injury								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Muscle injury								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Muscle strain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Overdose								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Product administration error								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Skin abrasion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Skin laceration								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Spinal column injury								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Spinal compression fracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Subcutaneous haematoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Subdural haematoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Thermal burn								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Tooth fracture								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Vaccination complication								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				3	(1.3)	3	2.25
Wound								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Wrong product administered								
<10 years	0				0			
>=10 years	1	(0.4)	2	1.48	1	(0.4)	1	0.75
Investigations								
All								
<10 years	4	(7.1)	4	12.53	0			
>=10 years	8	(3.4)	11	8.12	13	(5.7)	14	10.50
Amylase increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Blood alkaline phosphatase increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Blood creatinine increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Blood pressure increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Blood triglycerides increased								

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Blood urine present								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Catheterisation cardiac								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Electrocardiogram abnormal								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Electrocardiogram T wave inversion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Eosinophil count increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Glomerular filtration rate decreased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Haematocrit increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Haemoglobin increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Liver function test abnormal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Liver function test increased								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Platelet count decreased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
SARS-CoV-2 test positive								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Transaminases increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Weight increased								
<10 years	3	(5.4)	3	9.40	0			
>=10 years	3	(1.3)	3	2.22	4	(1.7)	4	3.00

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<10 years	2	(3.6)	3	9.40	6	(9.8)	6	17.91
>=10 years	13	(5.5)	15	11.08	14	(6.1)	16	12.00
Decreased appetite								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Dehydration								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Dyslipidaemia								
<10 years	1	(1.8)	2	6.27	1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	2	(0.9)	2	1.50
Fluid retention								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hypercholesterolaemia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Hyperglycaemia								
<10 years	0				0			
>=10 years	0				5	(2.2)	5	3.75
Hyperkalaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	4	(1.7)	4	3.00
Hypertriglyceridaemia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Hypoalbuminaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hypoglycaemia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	3	(1.3)	3	2.22	1	(0.4)	1	0.75
Hypokalaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Hyponatraemia								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Increased appetite								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipomatosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Vitamin D deficiency								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Musculoskeletal and connective tissue disorders								
All								
<10 years	4	(7.1)	4	12.53	8	(13.1)	12	35.82
>=10 years	28	(11.9)	37	27.32	27	(11.7)	36	27.01
Arthralgia								
<10 years	2	(3.6)	2	6.27	1	(1.6)	1	2.99
>=10 years	3	(1.3)	4	2.95	5	(2.2)	5	3.75
Arthritis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				1	(0.4)	1	0.75
Back disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Back pain								
<10 years	1	(1.8)	1	3.13	3	(4.9)	3	8.96
>=10 years	7	(3.0)	7	5.17	8	(3.5)	8	6.00
Bone cyst								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Bone pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Coccydynia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Flank pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Foot deformity								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Intervertebral disc protrusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Jaw disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle spasms								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	2	(0.9)	2	1.50
Myalgia								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Myositis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Neck pain								
<10 years	0				0			
>=10 years	4	(1.7)	4	2.95	1	(0.4)	1	0.75
Osteoarthritis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	5	(2.1)	5	3.69	6	(2.6)	7	5.25
Osteochondrosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Pain in extremity								
<10 years	0				1	(1.6)	2	5.97
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Periarthritis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Periostitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Rotator cuff syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Spinal osteoarthritis								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	0			
Tendon disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Tendonitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Tenosynovitis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Torticollis								
<10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.75
Trigger finger								
<10 years	0				0			
>=10 years	4	(1.7)	4	2.95	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	3	(1.3)	3	2.22	3	(1.3)	5	3.75
Adrenal adenoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Eye naevus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Lung adenocarcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Osteoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pancreatic neoplasm								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Small cell lung cancer								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Small intestine neuroendocrine tumour								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Uterine cancer								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Uterine leiomyoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Nervous system disorders								
All								
<10 years	5	(8.9)	8	25.06	5	(8.2)	8	23.88
>=10 years	14	(6.0)	24	17.72	24	(10.4)	39	29.26
Anosmia								
<10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.75
Basilar migraine								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Carpal tunnel syndrome								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	1	(0.4)	1	0.74	4	(1.7)	4	3.00
Cerebral arteriosclerosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Cerebrovascular accident								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Cerebrovascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Cognitive disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Diabetic neuropathy								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	2	(0.9)	2	1.50
Dizziness								
<10 years	2	(3.6)	5	15.66	0			
>=10 years	3	(1.3)	4	2.95	2	(0.9)	3	2.25
Dizziness postural								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Dysgeusia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Essential tremor								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Facial nerve disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Headache								
<10 years	2	(3.6)	2	6.27	2	(3.3)	4	11.94
>=10 years	6	(2.6)	8	5.91	7	(3.0)	8	6.00
Hemiparesis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Hypoaesthesia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Hypoglycaemic coma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Hyporeflexia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Memory impairment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Migraine								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Morton's neuralgia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Neuropathy peripheral								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Paraesthesia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				2	(0.9)	2	1.50
Sciatica								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Sleep deficit								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Transient ischaemic attack								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Tremor								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	6	4.50
Vascular encephalopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<10 years	0				2	(3.3)	2	5.97
>=10 years	2	(0.9)	2	1.48	7	(3.0)	7	5.25
Affect lability								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Depression								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Fear								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Insomnia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Mental status changes								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Mixed anxiety and depressive disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Phobia								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Sleep disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<10 years	0				2	(3.3)	2	5.97
>=10 years	4	(1.7)	7	5.17	4	(1.7)	4	3.00
Acute kidney injury								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Chronic kidney disease								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Dysuria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Haematuria								
<10 years	0				0			
>=10 years	1	(0.4)	2	1.48	0			
Hydrocalyx								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Nephropathy								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Renal colic								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Renal cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Reproductive system and breast disorders								
All								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Benign prostatic hyperplasia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Menopausal disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Respiratory, thoracic and mediastinal disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	4	(7.1)	4	12.53	4	(6.6)	4	11.94
>=10 years	13	(5.5)	16	11.81	15	(6.5)	19	14.25
Asthma								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Bronchitis chronic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Cough								
<10 years	0				0			
>=10 years	3	(1.3)	3	2.22	4	(1.7)	4	3.00
Dyspnoea								
<10 years	0				2	(3.3)	2	5.97
>=10 years	1	(0.4)	1	0.74	3	(1.3)	4	3.00
Emphysema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Epistaxis								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	2	1.50
Nasal congestion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Nasal septum deviation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Oropharyngeal pain								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Paranasal cyst								
<10 years	0				0			
>=10 years	0				2	(0.9)	2	1.50
Pleurisy								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Pulmonary fibrosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Pulmonary hypertension								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Respiratory disorder								
<10 years	2	(3.6)	2	6.27	0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis allergic								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Rhinorrhoea								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Sinus congestion								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				0			
Sinus pain								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Skin and subcutaneous tissue disorders								
All								
<10 years	0				1	(1.6)	2	5.97
>=10 years	12	(5.1)	13	9.60	14	(6.1)	14	10.50
Alopecia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Blister								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Cold sweat								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Dermatitis contact								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Eczema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	2	(0.9)	2	1.50
Hyperhidrosis								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Hyperkeratosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Intertrigo								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Lipohypertrophy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pruritus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	3	(1.3)	3	2.25
Rash								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Seborrhoea								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Skin reaction								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Skin ulcer								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	1	(0.4)	1	0.75
Umbilical haematoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Urticaria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Surgical and medical procedures								
All								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	0			
Cardiac pacemaker replacement								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Shoulder operation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Tooth extraction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Vascular disorders								
All								
<10 years	1	(1.8)	1	3.13	3	(4.9)	4	11.94
>=10 years	7	(3.0)	11	8.12	13	(5.7)	15	11.25
Aortic arteriosclerosis								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Blood pressure fluctuation								
<10 years	0				1	(1.6)	1	2.99
>=10 years	0				0			
Deep vein thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Diabetic vascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	1	(0.4)	1	0.75
Haematoma								
<10 years	0				1	(1.6)	1	2.99
>=10 years	1	(0.4)	1	0.74	0			
Hypertension								
<10 years	0				1	(1.6)	1	2.99
>=10 years	2	(0.9)	2	1.48	5	(2.2)	5	3.75
Hypertensive crisis								
<10 years	1	(1.8)	1	3.13	0			
>=10 years	0				1	(0.4)	3	2.25
Hypertensive urgency								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Hypotension								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Neovascularisation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75
Orthostatic hypotension								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Peripheral arterial occlusive disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Peripheral artery stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	3	2.22	0			
Peripheral venous disease								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.74	0			
Thrombophlebitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

7.16.32 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	75				82			
>=10 years	215				210			
PYE (years)								
<10 years	37.23				40.36			
>=10 years	105.08				103.76			
Events								
<10 years	46	(61.3)	135	362.62	51	(62.2)	149	369.19
>=10 years	143	(66.5)	372	354.02	139	(66.2)	470	452.96
Blood and lymphatic system disorders								
All								
<10 years	0				0			
>=10 years	3	(1.4)	3	2.86	3	(1.4)	3	2.89
Anaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Iron deficiency anaemia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Lymphadenitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Lymphadenopathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Thrombocytopenia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
<10 years	3	(4.0)	3	8.06	2	(2.4)	2	4.96
>=10 years	6	(2.8)	6	5.71	3	(1.4)	4	3.85
Angina pectoris								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Angina unstable								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Atrial fibrillation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Bundle branch block right								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	0				0			
Cardiac failure								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Cardiomegaly								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Cardiovascular disorder								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Myocardial ischaemia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Palpitations								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Ventricular extrasystoles								
<10 years	0				0			
>=10 years	3	(1.4)	3	2.86	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	2	(1.0)	2	1.93
Deafness neurosensory								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Ear pain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Vertigo								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Endocrine disorders								
All								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Hypothyroidism								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Eye disorders								
All								
<10 years	2	(2.7)	2	5.37	3	(3.7)	4	9.91
>=10 years	27	(12.6)	35	33.31	25	(11.9)	33	31.80
Arteriosclerotic retinopathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Astigmatism								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Cataract								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	3	(1.4)	3	2.86	2	(1.0)	2	1.93
Cataract nuclear								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Conjunctival haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Corneal erosion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Diabetic retinal oedema								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Diabetic retinopathy								
<10 years	0				1	(1.2)	1	2.48
>=10 years	12	(5.6)	12	11.42	13	(6.2)	13	12.53
Dry eye								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Epiretinal membrane								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Glaucoma								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				3	(1.4)	3	2.89
Macular oedema								
<10 years	0				0			
>=10 years	3	(1.4)	4	3.81	1	(0.5)	1	0.96
Myopia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Non-proliferative retinopathy								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	2	(1.0)	2	1.93
Ocular hypertension								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.93
Photopsia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Posterior capsule opacification								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Presbyopia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Pterygium								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal vascular disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Retinopathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Retinopathy hypertensive								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	0			
Vision blurred								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	0			
Vitreous detachment								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Vitreous floaters								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Gastrointestinal disorders								
All								
<10 years	6	(8.0)	9	24.17	8	(9.8)	13	32.21
>=10 years	20	(9.3)	29	27.60	16	(7.6)	28	26.98
Abdominal discomfort								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Abdominal distension								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Abdominal pain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Abdominal pain upper								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	0			
Anal fissure								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Chronic gastritis								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Constipation								
<10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.5)	1	0.95	0			
Dental caries								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Diarrhoea								
<10 years	2	(2.7)	3	8.06	2	(2.4)	2	4.96
>=10 years	3	(1.4)	3	2.86	2	(1.0)	3	2.89
Diverticulum intestinal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Dyspepsia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Faeces soft								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Gastric polyps								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Gastritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Gastritis erosive								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Gastrooesophageal reflux disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Gingival recession								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.93
Haemorrhoids								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hiatus hernia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Impaired gastric emptying								
<10 years	0				0			
>=10 years	1	(0.5)	2	1.90	0			
Irritable bowel syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lumbar hernia								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Nausea								
<10 years	1	(1.3)	1	2.69	3	(3.7)	3	7.43
>=10 years	3	(1.4)	3	2.86	5	(2.4)	5	4.82
Odynophagia								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Pancreatic failure								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Pneumatosis intestinalis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Toothache								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	2	(1.0)	4	3.85
Vomiting								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	6	(2.8)	6	5.71	4	(1.9)	4	3.85
General disorders and administration site conditions								
All								
<10 years	8	(10.7)	9	24.17	12	(14.6)	17	42.12
>=10 years	33	(15.3)	41	39.02	22	(10.5)	66	63.61
Asthenia								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Chest pain								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Fatigue								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	4	(1.9)	5	4.76	1	(0.5)	1	0.96
Hunger								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	2	1.93
Hyperthermia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inflammation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Influenza like illness								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Injection site mass								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Injection site pain								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Injection site urticaria								
<10 years	1	(1.3)	2	5.37	0			
>=10 years	0				0			
Malaise								
<10 years	1	(1.3)	1	2.69	1	(1.2)	4	9.91
>=10 years	2	(0.9)	2	1.90	2	(1.0)	40	38.55
Medical device site bruise								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	0			
Medical device site dermatitis								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	2	(1.0)	3	2.89
Medical device site erythema								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				2	(1.0)	3	2.89
Medical device site haematoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Medical device site haemorrhage								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Medical device site irritation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Medical device site pain								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Medical device site pruritus								
<10 years	0				2	(2.4)	2	4.96
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Medical device site rash								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(1.3)	1	2.69	4	(4.9)	4	9.91
>=10 years	5	(2.3)	5	4.76	3	(1.4)	3	2.89
Medical device site reaction								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	0			
Oedema peripheral								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Pain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	0			
Pyrexia								
<10 years	0				2	(2.4)	2	4.96
>=10 years	9	(4.2)	10	9.52	4	(1.9)	4	3.85
Swelling face								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Vaccination site pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hepatobiliary disorders								
All								
<10 years	0				0			
>=10 years	5	(2.3)	6	5.71	4	(1.9)	4	3.85
Gallbladder disorder								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Gallbladder polyp								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	2	(1.0)	2	1.93
Hepatic calcification								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hepatic steatosis								
<10 years	0				0			
>=10 years	3	(1.4)	3	2.86	1	(0.5)	1	0.96
Hypertransaminasaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Hypersensitivity								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	0			
Seasonal allergy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Infections and infestations								
All								
<10 years	24	(32.0)	35	94.01	27	(32.9)	41	101.59
>=10 years	80	(37.2)	112	106.59	74	(35.2)	107	103.12
Abscess limb								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	2	1.93
Acute sinusitis								
<10 years	0				2	(2.4)	2	4.96
>=10 years	0				1	(0.5)	1	0.96
Breast abscess								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Bronchitis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	3	(1.4)	3	2.86	2	(1.0)	2	1.93
Conjunctivitis								
<10 years	0				0			
>=10 years	4	(1.9)	4	3.81	0			
Coronavirus infection								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
COVID-19								
<10 years	3	(4.0)	4	10.74	11	(13.4)	12	29.73
>=10 years	26	(12.1)	26	24.74	21	(10.0)	22	21.20
COVID-19 pneumonia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Cystitis escherichia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Eye infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Fungal skin infection								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Gastric infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Gastroenteritis								
<10 years	0				0			
>=10 years	6	(2.8)	7	6.66	2	(1.0)	2	1.93
Gastroenteritis viral								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				2	(1.0)	2	1.93
Gastrointestinal infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	2	(1.0)	3	2.89
Genital infection fungal								
<10 years	0				0			
>=10 years	1	(0.5)	2	1.90	0			
Gingivitis								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Herpes zoster								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	2	(1.0)	2	1.93
Hordeolum								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				1	(0.5)	1	0.96
Infected cyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Influenza								
<10 years	0				3	(3.7)	3	7.43
>=10 years	1	(0.5)	1	0.95	2	(1.0)	2	1.93

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Localised infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Lower respiratory tract infection								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Nasopharyngitis								
<10 years	11	(14.7)	15	40.29	8	(9.8)	10	24.78
>=10 years	23	(10.7)	27	25.70	28	(13.3)	33	31.80
Norovirus infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Otitis externa								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	2.89
Otitis media								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Periodontitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Pharyngitis								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	4	(1.9)	4	3.81	0			
Pneumonia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Respiratory tract infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Respiratory tract infection viral								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Rhinitis								
<10 years	0				1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	3	(1.4)	4	3.85
Severe acute respiratory syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinusitis								
<10 years	1	(1.3)	1	2.69	2	(2.4)	2	4.96
>=10 years	4	(1.9)	4	3.81	0			
Skin infection								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Tinea cruris								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Tinea pedis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				1	(0.5)	1	0.96
Tonsillitis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Tooth abscess								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	0			
Tooth infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Upper respiratory tract infection								
<10 years	2	(2.7)	2	5.37	1	(1.2)	2	4.96
>=10 years	4	(1.9)	4	3.81	6	(2.9)	6	5.78
Urinary tract infection								
<10 years	1	(1.3)	1	2.69	1	(1.2)	2	4.96
>=10 years	5	(2.3)	5	4.76	5	(2.4)	6	5.78
Vaginal infection								
<10 years	0				0			
>=10 years	1	(0.5)	2	1.90	0			
Viral infection								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	3	(1.4)	3	2.89
Vulvitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Vulvovaginitis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Injury, poisoning and procedural complications								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	8	(10.7)	13	34.92	13	(15.9)	15	37.17
>=10 years	22	(10.2)	24	22.84	20	(9.5)	24	23.13
Accidental overdose								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	6	(2.8)	7	6.66	1	(0.5)	1	0.96
Anaemia postoperative								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Animal scratch								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Arthropod bite								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Back injury								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Burns first degree								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Clavicle fracture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Contusion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	2	(1.0)	2	1.93
Corneal abrasion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Epicondylitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Face injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Fall								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Fibula fracture								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Hand fracture								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Heat stroke								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Incorrect dose administered								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	0			
Joint injury								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Ligament sprain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	0			
Limb injury								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Medication error								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Muscle strain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Nerve injury								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Prescribed overdose								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	4	(1.9)	4	3.81	0			
Procedural pain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Product administration error								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Product dispensing error								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Radius fracture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Road traffic accident								
<10 years	1	(1.3)	2	5.37	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Skin abrasion								
<10 years	1	(1.3)	2	5.37	0			
>=10 years	0				1	(0.5)	1	0.96
Skin laceration								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Tooth fracture								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Vaccination complication								
<10 years	1	(1.3)	1	2.69	5	(6.1)	7	17.34
>=10 years	4	(1.9)	4	3.81	3	(1.4)	4	3.85
Wound								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Wound dehiscence								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Wrong product administered								
<10 years	0				2	(2.4)	2	4.96
>=10 years	0				2	(1.0)	2	1.93
Investigations								
All								
<10 years	5	(6.7)	5	13.43	2	(2.4)	2	4.96
>=10 years	9	(4.2)	10	9.52	11	(5.2)	13	12.53
Angiogram								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Aspartate aminotransferase increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Blood cholesterol increased								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Blood glucose increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Blood pressure increased								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood testosterone decreased								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Blood triglycerides increased								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Blood uric acid increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Cardiac murmur								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Electrocardiogram abnormal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Eosinophil count increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.93
Haemoglobin decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Heart rate increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hepatic enzyme increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Hepatitis B virus test positive								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Lipids abnormal								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Low density lipoprotein increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Mycobacterium tuberculosis complex test positive								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Occult blood positive								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
SARS-CoV-2 test positive								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				3	(1.4)	3	2.89
Weight decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Weight increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
White blood cell count decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Metabolism and nutrition disorders								
All								
<10 years	2	(2.7)	2	5.37	4	(4.9)	4	9.91
>=10 years	6	(2.8)	8	7.61	5	(2.4)	7	6.75
Dehydration								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	1.93
Hypercholesterolaemia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hyperuricaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hypoglycaemia								
<10 years	1	(1.3)	1	2.69	2	(2.4)	2	4.96
>=10 years	4	(1.9)	6	5.71	1	(0.5)	2	1.93
Hyponatraemia								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Insulin resistance								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Obesity								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Vitamin D deficiency								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Musculoskeletal and connective tissue disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	7	(9.3)	8	21.49	9	(11.0)	15	37.17
>=10 years	20	(9.3)	23	21.89	30	(14.3)	48	46.26
Arthralgia								
<10 years	1	(1.3)	1	2.69	4	(4.9)	4	9.91
>=10 years	5	(2.3)	5	4.76	5	(2.4)	5	4.82
Arthritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Back pain								
<10 years	2	(2.7)	2	5.37	1	(1.2)	2	4.96
>=10 years	1	(0.5)	1	0.95	10	(4.8)	23	22.17
Bursitis								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Chondromalacia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Groin pain								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Limb discomfort								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Limb mass								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Muscle spasms								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	0			
Muscular weakness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Musculoskeletal stiffness								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	0				0			
Myalgia								
<10 years	0				2	(2.4)	3	7.43
>=10 years	2	(0.9)	2	1.90	5	(2.4)	5	4.82
Neck pain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nodal osteoarthritis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Osteoarthritis								
<10 years	2	(2.7)	2	5.37	1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Pain in extremity								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	5	(2.3)	5	4.76	5	(2.4)	5	4.82
Periarthritis								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	2.89
Rheumatoid arthritis								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Synovial cyst								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Tendonitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Tenosynovitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Trigger finger								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	3	(1.4)	3	2.86	2	(1.0)	3	2.89
Benign neoplasm of thyroid gland								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Benign renal neoplasm								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Eye naevus								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Haemangioma of liver								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Melanocytic naevus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Uterine leiomyoma								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Nervous system disorders								
All								
<10 years	11	(14.7)	28	75.21	5	(6.1)	6	14.87
>=10 years	16	(7.4)	18	17.13	19	(9.0)	72	69.39
Autonomic nervous system imbalance								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Burning sensation								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Carpal tunnel syndrome								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Cervicobrachial syndrome								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			

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Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic neuropathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Disturbance in attention								
<10 years	1	(1.3)	9	24.17	0			
>=10 years	0				0			
Dizziness								
<10 years	1	(1.3)	2	5.37	0			
>=10 years	1	(0.5)	1	0.95	2	(1.0)	3	2.89
Dizziness postural								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Encephalopathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Haemorrhage intracranial								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Headache								
<10 years	6	(8.0)	10	26.86	3	(3.7)	4	9.91
>=10 years	7	(3.3)	9	8.57	7	(3.3)	9	8.67
Hypoaesthesia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hypoglycaemic seizure								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				1	(0.5)	1	0.96
Hypoglycaemic unconsciousness								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hypotonia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Loss of consciousness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Migraine								
<10 years	1	(1.3)	2	5.37	1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Neuropathy peripheral								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post herpetic neuralgia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Sinus headache								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Somnolence								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Speech disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Syncope								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Tremor								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				2	(1.0)	49	47.22
Psychiatric disorders								
All								
<10 years	3	(4.0)	3	8.06	4	(4.9)	5	12.39
>=10 years	2	(0.9)	2	1.90	2	(1.0)	2	1.93
Anxiety								
<10 years	0				2	(2.4)	2	4.96
>=10 years	1	(0.5)	1	0.95	2	(1.0)	2	1.93
Attention deficit hyperactivity disorder								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Depressed mood								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Depression								
<10 years	0				3	(3.7)	3	7.43
>=10 years	0				0			
Insomnia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Sleep disorder								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<10 years	2	(2.7)	2	5.37	1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	2	(1.0)	5	4.82
Chronic kidney disease								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Diabetic nephropathy								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				1	(0.5)	1	0.96
Hydrocalyx								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Hypertensive nephropathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Microalbuminuria								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			
Renal cyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Renal pain								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<10 years	0				2	(2.4)	4	9.91
>=10 years	4	(1.9)	4	3.81	2	(1.0)	2	1.93
Benign prostatic hyperplasia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Dysmenorrhoea								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Ectropion of cervix								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Fibrocystic breast disease								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Ovarian disorder								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Penile pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Premenstrual syndrome								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Prostatomegaly								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Respiratory, thoracic and mediastinal disorders								
All								
<10 years	5	(6.7)	7	18.80	5	(6.1)	5	12.39
>=10 years	16	(7.4)	19	18.08	16	(7.6)	24	23.13
Allergic cough								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Bronchial hyperreactivity								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cough								
<10 years	1	(1.3)	2	5.37	0			
>=10 years	2	(0.9)	3	2.86	8	(3.8)	9	8.67
Dyspnoea exertional								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Epistaxis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hiccups								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Nasal congestion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Oropharyngeal pain								
<10 years	0				1	(1.2)	1	2.48
>=10 years	5	(2.3)	5	4.76	2	(1.0)	2	1.93
Pleurisy								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Productive cough								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Pulmonary congestion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Respiratory disorder								
<10 years	3	(4.0)	3	8.06	1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Rhinitis allergic								
<10 years	0				1	(1.2)	1	2.48
>=10 years	1	(0.5)	1	0.95	0			
Rhinorrhoea								
<10 years	0				1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	5	(2.4)	5	4.82
Sinus congestion								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Sneezing								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Throat irritation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Upper-airway cough syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Skin and subcutaneous tissue disorders								
All								
<10 years	4	(5.3)	4	10.74	6	(7.3)	12	29.73
>=10 years	20	(9.3)	20	19.03	18	(8.6)	20	19.27
Alopecia								
<10 years	0				0			
>=10 years	3	(1.4)	3	2.86	0			
Angioedema								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Blister								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Chronic spontaneous urticaria								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Cold sweat								
<10 years	0				2	(2.4)	6	14.87
>=10 years	0				3	(1.4)	3	2.89
Dermal cyst								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	0				1	(0.5)	1	0.96
Dermatitis								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	3	(1.4)	3	2.86	1	(0.5)	1	0.96
Dermatitis atopic								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	1.93
Dermatitis contact								
<10 years	0				1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	5	(2.4)	5	4.82
Dry skin								
<10 years	1	(1.3)	1	2.69	1	(1.2)	1	2.48
>=10 years	0				0			
Eczema								
<10 years	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.5)	1	0.96
Erythema								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Hidradenitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hyperkeratosis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Ingrown hair								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Lichen sclerosus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Macule								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Pruritus								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96
Rash								
<10 years	1	(1.3)	1	2.69	0			
>=10 years	2	(0.9)	2	1.90	0			
Rash erythematous								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Skin irritation								
<10 years	0				1	(1.2)	1	2.48
>=10 years	2	(0.9)	2	1.90	0			
Skin lesion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	1	(0.5)	1	0.96
Telangiectasia								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				0			
Urticaria								
<10 years	0				1	(1.2)	1	2.48
>=10 years	0				2	(1.0)	2	1.93
Xeroderma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<10 years	0				0			
>=10 years	2	(0.9)	2	1.90	0			
Cardiac ablation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Skin neoplasm excision								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Vascular disorders								
All								
<10 years	3	(4.0)	3	8.06	2	(2.4)	2	4.96
>=10 years	3	(1.4)	3	2.86	2	(1.0)	2	1.93
Arteriosclerosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.95	0			
Hypertension								
<10 years	3	(4.0)	3	8.06	2	(2.4)	2	4.96
>=10 years	2	(0.9)	2	1.90	1	(0.5)	1	0.96
Varicose vein								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.96

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.33 Adverse events by baseline BMI group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	87				80			
>=25 - <30	164				171			
>=30 - <35	162				146			
>=35	79				95			
PYE (years)								
<25	86.05				77.29			
>=25 - <30	162.45				170.12			
>=30 - <35	160.04				144.48			
>=35	77.33				93.15			
Events								
<25	65	(74.7)	197	228.93	51	(63.8)	145	187.61
>=25 - <30	117	(71.3)	412	253.61	117	(68.4)	396	232.77
>=30 - <35	111	(68.5)	431	269.31	104	(71.2)	378	261.63
>=35	58	(73.4)	187	241.81	63	(66.3)	243	260.88
Serious								
Yes								
<25	9	(10.3)	9	10.46	4	(5.0)	5	6.47
>=25 - <30	16	(9.8)	29	17.85	19	(11.1)	26	15.28
>=30 - <35	19	(11.7)	24	15.00	14	(9.6)	27	18.69
>=35	7	(8.9)	12	15.52	12	(12.6)	15	16.10
No								
<25	64	(73.6)	188	218.47	51	(63.8)	140	181.14
>=25 - <30	112	(68.3)	383	235.76	113	(66.1)	370	217.49
>=30 - <35	106	(65.4)	407	254.31	104	(71.2)	351	242.94
>=35	56	(70.9)	175	226.29	60	(63.2)	228	244.77
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	3	(3.4)	3	3.49	3	(3.8)	4	5.18
>=25 - <30	7	(4.3)	10	6.16	6	(3.5)	7	4.11
>=30 - <35	6	(3.7)	9	5.62	7	(4.8)	18	12.46
>=35	2	(2.5)	4	5.17	4	(4.2)	5	5.37
Moderate								
<25	25	(28.7)	43	49.97	20	(25.0)	28	36.23
>=25 - <30	51	(31.1)	91	56.02	44	(25.7)	77	45.26
>=30 - <35	45	(27.8)	88	54.99	49	(33.6)	93	64.37
>=35	31	(39.2)	58	75.00	23	(24.2)	53	56.90
Mild								
<25	56	(64.4)	151	175.47	42	(52.5)	113	146.21
>=25 - <30	101	(61.6)	311	191.44	102	(59.6)	312	183.40
>=30 - <35	89	(54.9)	334	208.70	87	(59.6)	267	184.80
>=35	46	(58.2)	125	161.64	55	(57.9)	185	198.61
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	3	(3.4)	8	9.30	4	(5.0)	4	5.18
>=25 - <30	9	(5.5)	11	6.77	15	(8.8)	29	17.05
>=30 - <35	3	(1.9)	3	1.87	6	(4.1)	7	4.84
>=35	4	(5.1)	5	6.47	4	(4.2)	5	5.37
Possible								
<25	4	(4.6)	5	5.81	8	(10.0)	15	19.41
>=25 - <30	17	(10.4)	25	15.39	10	(5.8)	11	6.47
>=30 - <35	9	(5.6)	12	7.50	9	(6.2)	13	9.00
>=35	4	(5.1)	4	5.17	4	(4.2)	7	7.51
Unlikely								
<25	64	(73.6)	184	213.82	48	(60.0)	126	163.03
>=25 - <30	113	(68.9)	376	231.45	111	(64.9)	355	208.67
>=30 - <35	109	(67.3)	415	259.31	104	(71.2)	358	247.79
>=35	57	(72.2)	178	230.17	62	(65.3)	231	247.99
Missing								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
No								
<25	65	(74.7)	197	228.93	51	(63.8)	145	187.61
>=25 - <30	117	(71.3)	412	253.61	117	(68.4)	395	232.19
>=30 - <35	110	(67.9)	430	268.69	104	(71.2)	378	261.63
>=35	58	(73.4)	187	241.81	63	(66.3)	243	260.88
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	1	(1.1)	1	1.16	1	(1.3)	2	2.59
>=25 - <30	2	(1.2)	3	1.85	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Not recovered/not resolved								
<25	27	(31.0)	50	58.10	25	(31.3)	34	43.99
>=25 - <30	50	(30.5)	106	65.25	54	(31.6)	96	56.43
>=30 - <35	55	(34.0)	115	71.86	49	(33.6)	107	74.06
>=35	25	(31.6)	53	68.53	31	(32.6)	53	56.90
Recovered/resolved with sequelae								
<25	3	(3.4)	3	3.49	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	3	(2.1)	4	2.77
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Recovering/resolving								
<25	4	(4.6)	5	5.81	3	(3.8)	3	3.88
>=25 - <30	6	(3.7)	6	3.69	5	(2.9)	5	2.94
>=30 - <35	7	(4.3)	13	8.12	6	(4.1)	7	4.84
>=35	2	(2.5)	2	2.59	6	(6.3)	6	6.44
Recovered/resolved								
<25	58	(66.7)	138	160.37	46	(57.5)	106	137.15
>=25 - <30	103	(62.8)	297	182.82	96	(56.1)	294	172.82
>=30 - <35	95	(58.6)	300	187.46	92	(63.0)	259	179.26
>=35	52	(65.8)	131	169.40	59	(62.1)	183	196.46
Unknown								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.34 Adverse events by baseline BMI group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	54				56			
>=25 - <30	92				104			
>=30 - <35	69				63			
>=35	47				40			
PYE (years)								
<25	31.79				31.52			
>=25 - <30	54.34				60.73			
>=30 - <35	40.99				37.01			
>=35	28.12				23.50			
Events								
<25	30	(55.6)	81	254.78	24	(42.9)	49	155.44
>=25 - <30	55	(59.8)	129	237.39	50	(48.1)	106	174.54
>=30 - <35	40	(58.0)	133	324.44	38	(60.3)	100	270.18
>=35	36	(76.6)	123	437.40	22	(55.0)	73	310.58
Serious								
Yes								
<25	4	(7.4)	4	12.58	4	(7.1)	7	22.21
>=25 - <30	6	(6.5)	8	14.72	6	(5.8)	6	9.88
>=30 - <35	8	(11.6)	13	31.71	4	(6.3)	5	13.51
>=35	4	(8.5)	5	17.78	2	(5.0)	2	8.51
No								
<25	30	(55.6)	77	242.20	23	(41.1)	42	133.23
>=25 - <30	53	(57.6)	121	222.67	48	(46.2)	100	164.66
>=30 - <35	40	(58.0)	120	292.73	36	(57.1)	95	256.67
>=35	35	(74.5)	118	419.62	21	(52.5)	71	302.07
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	2	(3.7)	2	6.29	2	(3.6)	2	6.34
>=25 - <30	3	(3.3)	4	7.36	4	(3.8)	5	8.23
>=30 - <35	5	(7.2)	9	21.95	3	(4.8)	4	10.81
>=35	1	(2.1)	2	7.11	2	(5.0)	2	8.51
Moderate								
<25	9	(16.7)	13	40.89	8	(14.3)	13	41.24
>=25 - <30	17	(18.5)	22	40.49	16	(15.4)	18	29.64
>=30 - <35	17	(24.6)	44	107.33	20	(31.7)	29	78.35
>=35	21	(44.7)	43	152.91	10	(25.0)	22	93.60
Mild								
<25	26	(48.1)	66	207.60	19	(33.9)	34	107.86
>=25 - <30	45	(48.9)	103	189.54	43	(41.3)	83	136.67
>=30 - <35	33	(47.8)	80	195.15	27	(42.9)	67	181.02
>=35	28	(59.6)	78	277.38	20	(50.0)	49	208.47
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	2	(3.7)	2	6.29	1	(1.8)	5	15.86
>=25 - <30	3	(3.3)	3	5.52	4	(3.8)	7	11.53
>=30 - <35	4	(5.8)	4	9.76	0			
>=35	0				1	(2.5)	1	4.25
Possible								
<25	2	(3.7)	4	12.58	1	(1.8)	1	3.17
>=25 - <30	5	(5.4)	7	12.88	3	(2.9)	3	4.94
>=30 - <35	5	(7.2)	6	14.64	3	(4.8)	3	8.11
>=35	4	(8.5)	9	32.01	0			
Unlikely								
<25	29	(53.7)	71	223.33	23	(41.1)	42	133.23
>=25 - <30	51	(55.4)	117	215.31	49	(47.1)	95	156.43
>=30 - <35	39	(56.5)	122	297.61	36	(57.1)	96	259.37
>=35	36	(76.6)	111	394.73	22	(55.0)	72	306.32
Missing								
<25	2	(3.7)	4	12.58	1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	3	10.67	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt ; variable(s): OTMTDURY BMIG1BL ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & ANELFL == "Y" & ANL06FL == "Y"
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Adverse events by baseline BMI group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
No								
<25	30	(55.6)	77	242.20	23	(41.1)	48	152.27
>=25 - <30	54	(58.7)	126	231.87	50	(48.1)	105	172.89
>=30 - <35	40	(58.0)	132	322.00	36	(57.1)	97	262.07
>=35	36	(76.6)	119	423.18	22	(55.0)	73	310.58
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Missing								
<25	2	(3.7)	4	12.58	1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	3	10.67	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	0				1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	2	3.68	0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	0				0			
Not recovered/not resolved								
<25	15	(27.8)	30	94.36	9	(16.1)	11	34.89
>=25 - <30	18	(19.6)	26	47.85	21	(20.2)	29	47.75
>=30 - <35	12	(17.4)	23	56.11	12	(19.0)	14	37.82
>=35	10	(21.3)	18	64.01	6	(15.0)	9	38.29
Recovered/resolved with sequelae								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Recovering/resolving								
<25	2	(3.7)	5	15.73	3	(5.4)	3	9.52
>=25 - <30	8	(8.7)	8	14.72	4	(3.8)	4	6.59
>=30 - <35	4	(5.8)	5	12.20	5	(7.9)	5	13.51
>=35	5	(10.6)	6	21.34	4	(10.0)	5	21.27
Recovered/resolved								
<25	23	(42.6)	46	144.69	16	(28.6)	34	107.86
>=25 - <30	44	(47.8)	93	171.14	37	(35.6)	73	120.20
>=30 - <35	36	(52.2)	104	253.70	28	(44.4)	79	213.44
>=35	32	(68.1)	99	352.06	19	(47.5)	59	251.02
Unknown								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.35 Adverse events by baseline BMI group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	42				49			
>=25 - <30	95				96			
>=30 - <35	93				99			
>=35	61				47			
PYE (years)								
<25	23.95				28.37			
>=25 - <30	55.61				54.86			
>=30 - <35	53.13				56.58			
>=35	34.67				26.99			
Events								
<25	19	(45.2)	49	204.61	26	(53.1)	71	250.27
>=25 - <30	48	(50.5)	116	208.60	52	(54.2)	163	297.13
>=30 - <35	62	(66.7)	182	342.55	62	(62.6)	198	349.96
>=35	42	(68.9)	108	311.46	27	(57.4)	118	437.16
Serious								
Yes								
<25	3	(7.1)	3	12.53	4	(8.2)	5	17.62
>=25 - <30	6	(6.3)	8	14.39	4	(4.2)	4	7.29
>=30 - <35	6	(6.5)	15	28.23	10	(10.1)	13	22.98
>=35	7	(11.5)	9	25.96	7	(14.9)	11	40.75
No								
<25	19	(45.2)	46	192.08	24	(49.0)	66	232.64
>=25 - <30	47	(49.5)	108	194.21	50	(52.1)	159	289.84
>=30 - <35	58	(62.4)	167	314.32	59	(59.6)	185	326.98
>=35	40	(65.6)	99	285.51	27	(57.4)	107	396.41
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	2	(4.8)	2	8.35	3	(6.1)	3	10.57
>=25 - <30	2	(2.1)	2	3.60	3	(3.1)	3	5.47
>=30 - <35	5	(5.4)	10	18.82	5	(5.1)	7	12.37
>=35	4	(6.6)	6	17.30	1	(2.1)	1	3.70
Moderate								
<25	7	(16.7)	11	45.93	5	(10.2)	9	31.72
>=25 - <30	14	(14.7)	25	44.96	23	(24.0)	48	87.50
>=30 - <35	18	(19.4)	35	65.88	19	(19.2)	30	53.02
>=35	20	(32.8)	28	80.75	14	(29.8)	34	125.96
Mild								
<25	16	(38.1)	36	150.33	23	(46.9)	59	207.97
>=25 - <30	37	(38.9)	89	160.05	46	(47.9)	112	204.16
>=30 - <35	53	(57.0)	137	257.85	54	(54.5)	161	284.56
>=35	32	(52.5)	74	213.41	25	(53.2)	83	307.49
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	3	(3.2)	4	7.19	3	(3.1)	3	5.47
>=30 - <35	4	(4.3)	4	7.53	2	(2.0)	3	5.30
>=35	1	(1.6)	4	11.54	2	(4.3)	2	7.41
Possible								
<25	1	(2.4)	3	12.53	3	(6.1)	10	35.25
>=25 - <30	8	(8.4)	15	26.97	6	(6.3)	13	23.70
>=30 - <35	8	(8.6)	10	18.82	4	(4.0)	13	22.98
>=35	6	(9.8)	6	17.30	4	(8.5)	7	25.93
Unlikely								
<25	17	(40.5)	45	187.91	23	(46.9)	61	215.02
>=25 - <30	42	(44.2)	97	174.43	52	(54.2)	147	267.96
>=30 - <35	58	(62.4)	168	316.20	60	(60.6)	182	321.68
>=35	40	(65.6)	98	282.63	27	(57.4)	109	403.82
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	3	(3.1)	4	7.29
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	2	(3.3)	2	5.77	0			
No								
<25	19	(45.2)	49	204.61	26	(53.1)	71	250.27
>=25 - <30	48	(50.5)	115	206.80	52	(54.2)	158	288.01
>=30 - <35	62	(66.7)	180	338.79	62	(62.6)	198	349.96
>=35	41	(67.2)	106	305.70	27	(57.4)	118	437.16
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	3	5.65	0			
>=35	1	(1.6)	1	2.88	0			
Not recovered/not resolved								
<25	12	(28.6)	21	87.69	11	(22.4)	25	88.12
>=25 - <30	20	(21.1)	27	48.55	22	(22.9)	37	67.45
>=30 - <35	27	(29.0)	54	101.64	20	(20.2)	46	81.30
>=35	19	(31.1)	37	106.71	20	(42.6)	44	163.01
Recovered/resolved with sequelae								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Recovering/resolving								
<25	2	(4.8)	2	8.35	1	(2.0)	1	3.52
>=25 - <30	4	(4.2)	7	12.59	7	(7.3)	8	14.58
>=30 - <35	4	(4.3)	17	32.00	5	(5.1)	8	14.14
>=35	6	(9.8)	6	17.30	3	(6.4)	5	18.52
Recovered/resolved								
<25	13	(31.0)	26	108.57	19	(38.8)	44	155.10
>=25 - <30	37	(38.9)	82	147.46	47	(49.0)	117	213.28
>=30 - <35	56	(60.2)	108	203.27	52	(52.5)	143	252.75
>=35	37	(60.7)	64	184.57	24	(51.1)	69	255.63
Unknown								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.36 Adverse events by baseline BMI group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	105				135			
>=25 - <30	118				102			
>=30 - <35	46				41			
>=35	21				14			
PYE (years)								
<25	50.77				67.45			
>=25 - <30	58.04				49.72			
>=30 - <35	23.14				19.93			
>=35	10.36				7.01			
Events								
<25	56	(53.3)	153	301.35	83	(61.5)	345	511.47
>=25 - <30	83	(70.3)	217	373.88	72	(70.6)	183	368.05
>=30 - <35	36	(78.3)	106	458.08	27	(65.9)	71	356.22
>=35	14	(66.7)	31	299.31	8	(57.1)	20	285.13
Serious								
Yes								
<25	4	(3.8)	4	7.88	3	(2.2)	3	4.45
>=25 - <30	6	(5.1)	9	15.51	3	(2.9)	4	8.04
>=30 - <35	0				1	(2.4)	2	10.03
>=35	1	(4.8)	2	19.31	0			
No								
<25	54	(51.4)	149	293.48	81	(60.0)	342	507.02
>=25 - <30	81	(68.6)	208	358.38	71	(69.6)	179	360.00
>=30 - <35	36	(78.3)	106	458.08	27	(65.9)	69	346.18
>=35	14	(66.7)	29	280.00	8	(57.1)	20	285.13
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	3	(2.9)	3	5.91	2	(1.5)	2	2.97
>=25 - <30	6	(5.1)	7	12.06	1	(1.0)	1	2.01
>=30 - <35	0				1	(2.4)	2	10.03
>=35	0				0			
Moderate								
<25	12	(11.4)	21	41.36	19	(14.1)	42	62.27
>=25 - <30	26	(22.0)	44	75.81	22	(21.6)	30	60.34
>=30 - <35	11	(23.9)	20	86.43	6	(14.6)	12	60.21
>=35	2	(9.5)	5	48.28	4	(28.6)	5	71.28
Mild								
<25	49	(46.7)	129	254.08	78	(57.8)	301	446.24
>=25 - <30	71	(60.2)	166	286.01	63	(61.8)	152	305.70
>=30 - <35	35	(76.1)	86	371.65	22	(53.7)	57	285.98
>=35	14	(66.7)	26	251.03	7	(50.0)	15	213.85
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	5	(4.8)	5	9.85	5	(3.7)	6	8.90
>=25 - <30	10	(8.5)	13	22.40	1	(1.0)	1	2.01
>=30 - <35	2	(4.3)	2	8.64	1	(2.4)	1	5.02
>=35	0				0			
Possible								
<25	9	(8.6)	12	23.64	10	(7.4)	32	47.44
>=25 - <30	11	(9.3)	12	20.68	4	(3.9)	4	8.04
>=30 - <35	1	(2.2)	1	4.32	3	(7.3)	5	25.09
>=35	1	(4.8)	1	9.66	0			
Unlikely								
<25	53	(50.5)	136	267.87	83	(61.5)	307	455.14
>=25 - <30	76	(64.4)	192	330.81	71	(69.6)	178	357.99
>=30 - <35	35	(76.1)	103	445.11	27	(65.9)	65	326.12
>=35	14	(66.7)	30	289.65	8	(57.1)	20	285.13
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
No								
<25	56	(53.3)	153	301.35	83	(61.5)	345	511.47
>=25 - <30	83	(70.3)	217	373.88	72	(70.6)	183	368.05
>=30 - <35	36	(78.3)	106	458.08	27	(65.9)	71	356.22
>=35	14	(66.7)	31	299.31	8	(57.1)	20	285.13
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Not recovered/not resolved								
<25	23	(21.9)	39	76.82	44	(32.6)	76	112.67
>=25 - <30	37	(31.4)	60	103.38	22	(21.6)	43	86.48
>=30 - <35	18	(39.1)	27	116.68	11	(26.8)	19	95.33
>=35	8	(38.1)	8	77.24	6	(42.9)	6	85.54
Recovered/resolved with sequelae								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Recovering/resolving								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	3	(2.5)	3	5.17	2	(2.0)	3	6.03
>=30 - <35	2	(4.3)	2	8.64	1	(2.4)	1	5.02
>=35	0				1	(7.1)	3	42.77
Recovered/resolved								
<25	45	(42.9)	112	220.60	70	(51.9)	267	395.83
>=25 - <30	73	(61.9)	154	265.34	60	(58.8)	136	273.52
>=30 - <35	33	(71.7)	77	332.75	24	(58.5)	50	250.86
>=35	9	(42.9)	23	222.07	7	(50.0)	11	156.82
Unknown								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.37 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	87				80			
>=25 - <30	164				171			
>=30 - <35	162				146			
>=35	79				95			
PYE (years)								
<25	86.05				77.29			
>=25 - <30	162.45				170.12			
>=30 - <35	160.04				144.48			
>=35	77.33				93.15			
Events								
<25	65	(74.7)	197	228.93	51	(63.8)	145	187.61
>=25 - <30	117	(71.3)	412	253.61	117	(68.4)	396	232.77
>=30 - <35	111	(68.5)	431	269.31	104	(71.2)	378	261.63
>=35	58	(73.4)	187	241.81	63	(66.3)	243	260.88
Blood and lymphatic system disorders								
All								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	4	(2.3)	4	2.35
>=30 - <35	4	(2.5)	4	2.50	3	(2.1)	3	2.08
>=35	4	(5.1)	4	5.17	3	(3.2)	3	3.22
Anaemia								
<25	0				1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	2	(2.5)	2	2.59	2	(2.1)	2	2.15
Blood loss anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Eosinophilia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Hypochromic anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Iron deficiency anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Lymphadenopathy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Polycythaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Thrombocytopenia								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac disorders								
All								
<25	6	(6.9)	6	6.97	6	(7.5)	7	9.06
>=25 - <30	12	(7.3)	20	12.31	13	(7.6)	13	7.64
>=30 - <35	13	(8.0)	27	16.87	8	(5.5)	15	10.38
>=35	6	(7.6)	10	12.93	3	(3.2)	3	3.22
Acute coronary syndrome								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Acute myocardial infarction								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	0				2	(1.4)	2	1.38
>=35	2	(2.5)	2	2.59	0			
Angina pectoris								
<25	0				1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	0				0			
>=35	0				0			
Angina unstable								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Aortic valve calcification								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Aortic valve incompetence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Arrhythmia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Atrial fibrillation								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	5	(3.1)	6	3.75	2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	0			
Atrial flutter								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Atrial thrombosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Atrioventricular block complete								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Bradycardia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Bundle branch block right								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	2	1.38
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac dysfunction								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.87	0			
>=35	1	(1.3)	1	1.29	0			
Cardiac failure chronic								
<25	0				1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Cardiac failure congestive								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Cardiac ventricular thrombosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Chronic coronary syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Coronary artery disease								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	3	(1.9)	3	1.87	1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Coronary artery occlusion								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Diastolic dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Left atrial dilatation								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Left ventricular dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Left ventricular hypertrophy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Mitral valve incompetence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Myocardial infarction								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Myocardial ischaemia								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Palpitations								
<25	0				1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Pericardial effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Pericarditis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sinus arrhythmia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Sinus bradycardia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Sinus tachycardia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Supraventricular extrasystoles								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Tachycardia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Tricuspid valve incompetence								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Ventricular extrasystoles								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	3	(1.9)	3	1.87	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Congenital syphilitic osteochondritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Hydrocele								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Type V hyperlipidaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Ear and labyrinth disorders								
All								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	4	(2.4)	4	2.46	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	3	(2.1)	3	2.08
>=35	1	(1.3)	1	1.29	2	(2.1)	3	3.22
Ear inflammation								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Ear pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Eustachian tube dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoacusis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Presbyacusis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Tinnitus								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Vertigo								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	2	(2.1)	3	3.22
Vertigo positional								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				3	(1.8)	3	1.76
>=30 - <35	0				2	(1.4)	2	1.38
>=35	2	(2.5)	2	2.59	0			
Goitre								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Hyperplasia adrenal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hyperprolactinaemia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hyperthyroidism								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hypothyroidism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Thyroid mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(2.5)	2	2.59	0			
Eye disorders								
All								
<25	8	(9.2)	11	12.78	7	(8.8)	8	10.35
>=25 - <30	9	(5.5)	12	7.39	8	(4.7)	10	5.88
>=30 - <35	7	(4.3)	11	6.87	7	(4.8)	10	6.92
>=35	1	(1.3)	1	1.29	3	(3.2)	4	4.29

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acquired epiblepharon								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Asthenopia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Astigmatism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Blepharitis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Cataract								
<25	3	(3.4)	4	4.65	1	(1.3)	1	1.29
>=25 - <30	3	(1.8)	4	2.46	1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	1	(0.7)	1	0.69
>=35	0				1	(1.1)	2	2.15
Conjunctival erosion								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Conjunctival haemorrhage								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Conjunctivitis allergic								
<25	1	(1.1)	2	2.32	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dacryoadenitis acquired								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinal oedema								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinopathy								
<25	1	(1.1)	1	1.16	2	(2.5)	2	2.59
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Diplopia								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dry eye								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Eye discharge								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Eye inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Eye pain								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Glaucoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Macular oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal tension glaucoma								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ocular hypertension								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Optic disc vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Photophobia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Post thrombotic retinopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Posterior capsule opacification								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal aneurysm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Retinal artery occlusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Retinal detachment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal tear								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal vein occlusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Scintillating scotoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Uveitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vision blurred								
<25	0				1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Visual impairment								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Vitreous detachment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Vitreous haemorrhage								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal disorders								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	11	(12.6)	21	24.40	9	(11.3)	10	12.94
>=25 - <30	30	(18.3)	39	24.01	29	(17.0)	45	26.45
>=30 - <35	31	(19.1)	56	34.99	20	(13.7)	30	20.76
>=35	11	(13.9)	20	25.86	16	(16.8)	29	31.13
Abdominal discomfort								
<25	0				1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Abdominal distension								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Abdominal pain								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	3	(2.1)	3	2.08
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Abdominal pain lower								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Abdominal pain upper								
<25	0				0			
>=25 - <30	0				3	(1.8)	3	1.76
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	2	2.15
Acid peptic disease								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Anal fissure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Anal pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chronic gastritis								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Colitis								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Colitis ischaemic								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Colitis microscopic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Constipation								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	0			
Crohn's disease								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Dental caries								
<25	2	(2.3)	3	3.49	0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	2	2.59	1	(1.1)	1	1.07
Diarrhoea								
<25	4	(4.6)	6	6.97	1	(1.3)	1	1.29
>=25 - <30	10	(6.1)	11	6.77	8	(4.7)	8	4.70
>=30 - <35	13	(8.0)	20	12.50	6	(4.1)	7	4.84
>=35	4	(5.1)	6	7.76	6	(6.3)	6	6.44
Diverticulum								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diverticulum intestinal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Dry mouth								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Duodenitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Dyspepsia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Enteritis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Enterocolitis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	3	1.87	0			
>=35	0				0			
Epigastric discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Flatulence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	0			
Food poisoning								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Frequent bowel movements								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Gastric disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Gastric polyps								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Gastrointestinal inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Gastrooesophageal reflux disease								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	3	(2.1)	3	2.08
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Haematochezia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Haemorrhoids								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				1	(1.1)	1	1.07
Hiatus hernia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hyperaesthesia teeth								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperchlorhydria								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ileus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Inguinal hernia								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Intra-abdominal haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Irritable bowel syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Large intestine polyp								
<25	0				0			
>=25 - <30	0				2	(1.2)	3	1.76
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Loose tooth								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Melaena								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Nausea								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	6	(3.7)	6	3.69	2	(1.2)	2	1.18
>=30 - <35	7	(4.3)	8	5.00	2	(1.4)	4	2.77
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Pancreatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Pancreatitis acute								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Pancreatitis chronic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Periodontal disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Periodontal inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	1.38
>=35	0				0			
Rectal polyp								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Rectal prolapse								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Stomatitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Tooth impacted								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Toothache								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	3	(1.8)	3	1.85	1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	0			
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Ulcerative gastritis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Umbilical hernia								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Vomiting								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	2	(1.2)	2	1.23	4	(2.3)	5	2.94
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				4	(4.2)	6	6.44
General disorders and administration site conditions								
All								
<25	15	(17.2)	22	25.57	16	(20.0)	17	22.00
>=25 - <30	25	(15.2)	41	25.24	19	(11.1)	30	17.63
>=30 - <35	23	(14.2)	35	21.87	26	(17.8)	39	26.99
>=35	12	(15.2)	16	20.69	17	(17.9)	24	25.77
Asthenia								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	3	(1.8)	3	1.85	0			
>=30 - <35	0				3	(2.1)	3	2.08
>=35	0				1	(1.1)	1	1.07
Chest discomfort								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Chest pain								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	2	(1.2)	2	1.23	2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Chills								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Death								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Drug intolerance								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	0			
Early satiety								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Fatigue								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	4	(2.4)	4	2.46	0			
>=30 - <35	4	(2.5)	5	3.12	1	(0.7)	1	0.69
>=35	3	(3.8)	3	3.88	4	(4.2)	4	4.29
Feeling abnormal								
<25	1	(1.1)	3	3.49	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Feeling hot								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gait disturbance								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Hunger								
<25	0				1	(1.3)	1	1.29
>=25 - <30	5	(3.0)	6	3.69	0			
>=30 - <35	0				0			
>=35	0				0			
Implant site pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Influenza like illness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Injection site bruising								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				0			
Injection site dermatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Injection site erythema								
<25	0				0			
>=25 - <30	0				3	(1.8)	3	1.76
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Injection site haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Injection site hypersensitivity								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Injection site hypertrophy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Injection site mass								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Injection site pain								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Injection site reaction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Injection site urticaria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Malaise								
<25	2	(2.3)	2	2.32	2	(2.5)	2	2.59
>=25 - <30	3	(1.8)	4	2.46	3	(1.8)	4	2.35
>=30 - <35	0				3	(2.1)	4	2.77
>=35	0				0			
Medical device site bruise								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	1	(1.3)	2	2.59	0			
Medical device site dermatitis								
<25	1	(1.1)	1	1.16	3	(3.8)	3	3.88
>=25 - <30	0				1	(0.6)	4	2.35
>=30 - <35	1	(0.6)	4	2.50	2	(1.4)	5	3.46
>=35	0				2	(2.1)	2	2.15
Medical device site eczema								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Medical device site erythema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Medical device site haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Medical device site haemorrhage								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Medical device site hypersensitivity								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Medical device site inflammation								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Medical device site pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Medical device site pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.87	1	(0.7)	1	0.69
>=35	0				0			
Medical device site reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	3	3.88	1	(1.1)	1	1.07
Non-cardiac chest pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Oedema peripheral								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	4	(2.5)	4	2.50	3	(2.1)	4	2.77
>=35	0				1	(1.1)	1	1.07
Pain								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	3	(3.2)	3	3.22
Peripheral swelling								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Procedural failure								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Pyrexia								
<25	6	(6.9)	6	6.97	7	(8.8)	7	9.06
>=25 - <30	5	(3.0)	6	3.69	9	(5.3)	10	5.88
>=30 - <35	5	(3.1)	5	3.12	3	(2.1)	3	2.08
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15
Swelling								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Thirst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Vaccination site erythema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Vaccination site pain								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	1	(1.1)	1	1.16	0			
>=25 - <30	3	(1.8)	4	2.46	0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				1	(1.1)	1	1.07
Vaccination site reaction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatobiliary disorders								
All								
<25	1	(1.1)	2	2.32	0			
>=25 - <30	4	(2.4)	5	3.08	2	(1.2)	2	1.18
>=30 - <35	4	(2.5)	5	3.12	2	(1.4)	3	2.08
>=35	0				2	(2.1)	2	2.15
Cholelithiasis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Gallbladder cholesterolosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic cirrhosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Hepatic cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Hepatic function abnormal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hepatic steatosis								
<25	0				0			
>=25 - <30	3	(1.8)	3	1.85	1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypertransaminasaemia								
<25	1	(1.1)	2	2.32	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Liver disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Non-alcoholic steatohepatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Nonalcoholic fatty liver disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Steatohepatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Immune system disorders								
All								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	3	2.08
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15
Allergy to arthropod bite								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Immunisation reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	1.38
>=35	0				0			
Seasonal allergy								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infections and infestations								
All								
<25	32	(36.8)	46	53.46	29	(36.3)	37	47.87
>=25 - <30	54	(32.9)	83	51.09	59	(34.5)	87	51.14
>=30 - <35	51	(31.5)	83	51.86	65	(44.5)	93	64.37
>=35	32	(40.5)	51	65.95	40	(42.1)	70	75.15
Abscess								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Acarodermatitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Acute sinusitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Anal abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Asymptomatic COVID-19								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Bacterial infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Balanitis candida								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Body tinea								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Breast abscess								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Breast cellulitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Bronchitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	5	(3.0)	5	3.08	0			
>=30 - <35	1	(0.6)	1	0.62	3	(2.1)	3	2.08
>=35	2	(2.5)	2	2.59	0			
Candida infection								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Cellulitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Chlamydial infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Chronic hepatitis C								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Chronic sinusitis								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Chronic tonsillitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Clostridium difficile infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Conjunctivitis								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	2	(1.4)	2	1.38
>=35	0				0			
Coronavirus infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				2	(1.4)	3	2.08
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
COVID-19								
<25	10	(11.5)	10	11.62	11	(13.8)	11	14.23
>=25 - <30	14	(8.5)	14	8.62	20	(11.7)	20	11.76
>=30 - <35	13	(8.0)	13	8.12	12	(8.2)	12	8.31
>=35	12	(15.2)	12	15.52	18	(18.9)	19	20.40
COVID-19 pneumonia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	3	(1.9)	3	1.87	3	(2.1)	3	2.08
>=35	0				0			
Cystitis								
<25	4	(4.6)	5	5.81	3	(3.8)	3	3.88
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	3	2.08
>=35	0				2	(2.1)	2	2.15
Dermatophytosis of nail								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Diverticulitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Ear infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Empyema								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Endophthalmitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Epididymitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Erysipelas								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Escherichia urinary tract infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Eye infection bacterial								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Folliculitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Fungal balanitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Fungal infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Furuncle								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Gastroenteritis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	2	(1.2)	2	1.25	2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	0			
Gastroenteritis norovirus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Gastroenteritis viral								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Gastrointestinal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Genital infection fungal								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Giardiasis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Gingivitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	2	2.59	1	(1.1)	1	1.07
Helicobacter gastritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Helicobacter infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes dermatitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Herpes simplex								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Herpes virus infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Herpes zoster								
<25	0				3	(3.8)	3	3.88
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Hordeolum								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Infected bite								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Influenza								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				3	(2.1)	3	2.08
>=35	0				0			
Labyrinthitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Laryngitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	0				0			
Laryngopharyngitis								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Localised infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Lower respiratory tract infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	3	2.08
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Lyme disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Mastitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Nail infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Nasopharyngitis								
<25	11	(12.6)	12	13.94	6	(7.5)	6	7.76
>=25 - <30	9	(5.5)	12	7.39	13	(7.6)	15	8.82
>=30 - <35	7	(4.3)	8	5.00	11	(7.5)	11	7.61
>=35	3	(3.8)	4	5.17	4	(4.2)	5	5.37
Onychomycosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Oophoritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Oral herpes								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Oropharyngeal candidiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Osteomyelitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Otitis externa								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Otitis media								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Otitis media acute								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Otitis media chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Parotitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Peri-implantitis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pericoronitis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Periodontitis								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				1	(1.1)	1	1.07
Pharyngitis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	3	(1.8)	3	1.85	3	(1.8)	3	1.76
>=30 - <35	5	(3.1)	6	3.75	3	(2.1)	4	2.77
>=35	2	(2.5)	3	3.88	3	(3.2)	4	4.29
Pharyngotonsillitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Pneumonia								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Post procedural infection								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pulpitis dental								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Purulence								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Respiratory syncytial virus infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Respiratory tract infection								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(2.5)	2	2.59	3	(3.2)	3	3.22
Respiratory tract infection viral								
<25	1	(1.1)	1	1.16	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	0				0			
Rhinitis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	2	(1.2)	2	1.23	2	(1.2)	2	1.18
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Rotavirus infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Salpingitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Sepsis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Sinusitis								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	3	1.85	1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	2	(1.4)	3	2.08
>=35	1	(1.3)	1	1.29	2	(2.1)	3	3.22
Skin bacterial infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Skin infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Subcutaneous abscess								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Tinea infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(1.3)	1	1.29	0			
Tonsillitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Tooth abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	3	(2.1)	3	2.08
>=35	2	(2.5)	2	2.59	0			
Tooth infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Tracheitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Upper respiratory tract infection								
<25	3	(3.4)	3	3.49	2	(2.5)	2	2.59
>=25 - <30	7	(4.3)	10	6.16	3	(1.8)	3	1.76
>=30 - <35	8	(4.9)	11	6.87	3	(2.1)	3	2.08
>=35	5	(6.3)	6	7.76	5	(5.3)	6	6.44
Urethritis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Urinary tract infection								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	6	(3.5)	7	4.11
>=30 - <35	4	(2.5)	4	2.50	5	(3.4)	5	3.46
>=35	0				4	(4.2)	4	4.29
Vaginal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Varicella								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Viral pharyngitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Viral upper respiratory tract infection								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Vulvovaginal candidiasis								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	2	2.59	1	(1.1)	1	1.07
Vulvovaginal mycotic infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Injury, poisoning and procedural complications								
All								
<25	14	(16.1)	15	17.43	6	(7.5)	9	11.64
>=25 - <30	21	(12.8)	24	14.77	15	(8.8)	22	12.93
>=30 - <35	18	(11.1)	19	11.87	8	(5.5)	9	6.23
>=35	7	(8.9)	7	9.05	11	(11.6)	12	12.88
Accidental overdose								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Animal bite								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ankle fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Arthropod sting								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Bone contusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Burn oral cavity								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Burns first degree								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cervical vertebral fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Chillblains								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Contusion								
<25	2	(2.3)	2	2.32	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	3	1.87	1	(0.7)	1	0.69
>=35	0				0			
Deafness traumatic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Endotracheal intubation complication								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Fall								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Fibula fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Foot fracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Hand fracture								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Heat illness								
<25	1	(1.1)	1	1.16	1	(1.3)	2	2.59
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hip fracture								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Injury								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Joint injury								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Ligament sprain								
<25	1	(1.1)	1	1.16	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Limb injury								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	0			
Lower limb fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Meniscus injury								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Muscle strain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Overdose								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Post procedural fistula								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Post procedural haemorrhage								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Post procedural hypothyroidism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Post procedural stroke								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(1.1)	1	1.07
Post procedural swelling								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Procedural pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Radius fracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Rib fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Scar								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Skin abrasion								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(2.5)	2	2.59	0			
Skin laceration								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Soft tissue injury								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Thermal burn								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth fracture								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Traumatic haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Underdose								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Vaccination complication								
<25	2	(2.3)	2	2.32	2	(2.5)	2	2.59
>=25 - <30	7	(4.3)	7	4.31	4	(2.3)	8	4.70
>=30 - <35	1	(0.6)	1	0.62	4	(2.7)	5	3.46
>=35	0				3	(3.2)	4	4.29
Wound								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Wrist fracture								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Investigations								
All								
<25	6	(6.9)	6	6.97	2	(2.5)	2	2.59
>=25 - <30	7	(4.3)	9	5.54	7	(4.1)	7	4.11
>=30 - <35	6	(3.7)	7	4.37	10	(6.8)	11	7.61
>=35	2	(2.5)	2	2.59	2	(2.1)	2	2.15
Alanine aminotransferase increased								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Aspartate aminotransferase increased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood cholesterol increased								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Blood creatine increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Blood creatine phosphokinase increased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Blood glucose increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Blood pressure decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Blood pressure increased								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Blood triglycerides increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Body temperature increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Cardiac stress test abnormal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram repolarisation abnormality								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Glycosylated haemoglobin increased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Haemoglobin decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Hepatic enzyme increased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
International normalised ratio abnormal								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
International normalised ratio decreased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
International normalised ratio increased								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	0			
>=30 - <35	0				0			
>=35	0				0			
Lipids increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Red blood cell count decreased								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
SARS-CoV-2 test positive								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Transferrin saturation decreased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Weight decreased								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Weight increased								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	4	(2.7)	4	2.77
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15
Metabolism and nutrition disorders								
All								
<25	5	(5.7)	5	5.81	8	(10.0)	8	10.35
>=25 - <30	18	(11.0)	22	13.54	22	(12.9)	34	19.99
>=30 - <35	11	(6.8)	13	8.12	9	(6.2)	9	6.23
>=35	7	(8.9)	7	9.05	7	(7.4)	9	9.66
Appetite disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Decreased appetite								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Dehydration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Diabetes mellitus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Dyslipidaemia								
<25	2	(2.3)	2	2.32	1	(1.3)	1	1.29

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	5	(3.0)	5	3.08	4	(2.3)	4	2.35
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	2	(2.5)	2	2.59	0			
Electrolyte imbalance								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fluid retention								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Gout								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	2	1.25	2	(1.4)	2	1.38
>=35	0				1	(1.1)	1	1.07
Hypercholesterolaemia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Hyperglycaemia								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				3	(1.8)	3	1.76
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				0			
Hyperkalaemia								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	2	1.25	1	(0.7)	1	0.69
>=35	0				0			
Hyperlipidaemia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15
Hypertriglyceridaemia								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	3	(1.8)	3	1.85	2	(1.2)	2	1.18
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	0				0			
Hyperuricaemia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Hypoglycaemia								
<25	1	(1.1)	1	1.16	2	(2.5)	2	2.59
>=25 - <30	3	(1.8)	4	2.46	6	(3.5)	16	9.41
>=30 - <35	0				0			
>=35	0				1	(1.1)	2	2.15
Hypokalaemia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Increased appetite								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Iron deficiency								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Malnutrition								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Metabolic disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Obesity								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Vitamin D deficiency								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	2	(2.5)	2	2.59	0			
Zinc deficiency								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders								
All								
<25	12	(13.8)	13	15.11	11	(13.8)	15	19.41
>=25 - <30	32	(19.5)	57	35.09	26	(15.2)	37	21.75
>=30 - <35	40	(24.7)	63	39.37	32	(21.9)	50	34.61
>=35	15	(19.0)	23	29.74	23	(24.2)	31	33.28
Arthralgia								
<25	3	(3.4)	3	3.49	3	(3.8)	3	3.88
>=25 - <30	6	(3.7)	8	4.92	3	(1.8)	4	2.35
>=30 - <35	11	(6.8)	13	8.12	8	(5.5)	9	6.23
>=35	3	(3.8)	3	3.88	3	(3.2)	3	3.22
Arthritis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Axillary mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Back disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Back pain								
<25	4	(4.6)	4	4.65	3	(3.8)	4	5.18
>=25 - <30	11	(6.7)	13	8.00	5	(2.9)	5	2.94
>=30 - <35	9	(5.6)	9	5.62	8	(5.5)	8	5.54
>=35	3	(3.8)	3	3.88	8	(8.4)	8	8.59
Bone cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Bursitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Cervical spinal stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Chondropathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Coccydynia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Costochondritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Dupuytren's contracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Exostosis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Fibromyalgia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Fistula								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Flank pain								
<25	0				2	(2.5)	2	2.59
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Groin pain								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Intervertebral disc disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	0				0			
Intervertebral disc protrusion								
<25	0				0			
>=25 - <30	4	(2.4)	5	3.08	0			
>=30 - <35	0				2	(1.4)	3	2.08
>=35	0				1	(1.1)	1	1.07
Joint effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Joint swelling								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Limb deformity								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Lumbar spinal stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Mastication disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Muscle contracture								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Muscle spasms								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	2	(1.4)	2	1.38
>=35	3	(3.8)	3	3.88	1	(1.1)	1	1.07
Muscular weakness								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Musculoskeletal chest pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Musculoskeletal pain								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Musculoskeletal stiffness								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Myalgia								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Myositis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Neck pain								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	2	(1.4)	2	1.38
>=35	0				3	(3.2)	3	3.22
Osteoarthritis								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	4	(2.4)	5	3.08	3	(1.8)	4	2.35
>=30 - <35	4	(2.5)	5	3.12	5	(3.4)	5	3.46
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Osteochondrosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Osteopenia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Pain in extremity								
<25	0				0			
>=25 - <30	5	(3.0)	5	3.08	3	(1.8)	5	2.94
>=30 - <35	7	(4.3)	8	5.00	4	(2.7)	4	2.77
>=35	3	(3.8)	3	3.88	4	(4.2)	5	5.37
Periarthritis								
<25	1	(1.1)	1	1.16	3	(3.8)	3	3.88
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Plantar fasciitis								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	2	1.25	0			
>=35	0				0			
Polyarthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Rotator cuff syndrome								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Spinal osteoarthritis								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Spinal pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				2	(2.1)	2	2.15
Spinal stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Synovial cyst								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendonitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Tenosynovitis								
<25	0				0			
>=25 - <30	0				3	(1.8)	3	1.76
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	2	1.38
>=35	0				1	(1.1)	1	1.07
Tenosynovitis stenosans								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Trigger finger								
<25	0				0			
>=25 - <30	0				2	(1.2)	4	2.35
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Vertebral osteophyte								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	5	(3.0)	6	3.69	1	(0.6)	3	1.76
>=30 - <35	4	(2.5)	5	3.12	4	(2.7)	6	4.15
>=35	1	(1.3)	1	1.29	0			
Acrochordon								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Basal cell carcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	2	(1.4)	2	1.38
>=35	0				0			
Colon cancer								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Dysplastic naevus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Glioblastoma multiforme								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Haemangioma of liver								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatocellular carcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Malignant melanoma in situ								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Metastases to liver								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Neoplasm skin								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Oral fibroma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian cancer metastatic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pancreatic neoplasm								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Prostate cancer								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Renal cell carcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Salivary gland neoplasm								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Seborrhoeic keratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	2	1.25	0			
>=35	1	(1.3)	1	1.29	0			
Uterine leiomyoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Nervous system disorders								
All								
<25	8	(9.2)	10	11.62	6	(7.5)	8	10.35
>=25 - <30	20	(12.2)	28	17.24	23	(13.5)	28	16.46
>=30 - <35	28	(17.3)	36	22.49	17	(11.6)	26	18.00
>=35	9	(11.4)	13	16.81	21	(22.1)	23	24.69
Ageusia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Anosmia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Balance disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Brain injury								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Burning sensation								
<25	0				1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Carotid arteriosclerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Carpal tunnel syndrome								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	3	(1.9)	3	1.87	0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Cerebral atrophy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Cerebral haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Cerebrovascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Cervical radiculopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Diabetic neuropathy								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	2.15
Dizziness								
<25	1	(1.1)	3	3.49	1	(1.3)	1	1.29
>=25 - <30	4	(2.4)	4	2.46	4	(2.3)	5	2.94
>=30 - <35	5	(3.1)	7	4.37	4	(2.7)	4	2.77
>=35	2	(2.5)	2	2.59	5	(5.3)	5	5.37
Dizziness postural								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Dysgeusia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Headache								
<25	3	(3.4)	3	3.49	2	(2.5)	2	2.59
>=25 - <30	5	(3.0)	7	4.31	5	(2.9)	6	3.53
>=30 - <35	6	(3.7)	6	3.75	6	(4.1)	12	8.31
>=35	2	(2.5)	2	2.59	4	(4.2)	4	4.29
Hypoaesthesia								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	1	(0.6)	3	1.85	2	(1.2)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				1	(1.1)	1	1.07
Lethargy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				0			
Lumbar radiculopathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				1	(1.1)	1	1.07
Memory impairment								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Mental impairment								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Migraine								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Neuralgia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Neuroglycopenia								
<25	0				1	(1.3)	3	3.88
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Neuropathy peripheral								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Paraesthesia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	2	(2.5)	2	2.59	2	(2.1)	2	2.15
Parkinsonian gait								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Post herpetic neuralgia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Presyncope								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Sciatica								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	1	0.62	3	(1.8)	3	1.76
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	2	1.38
>=35	0				2	(2.1)	2	2.15

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Somnolence								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Syncope								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	3	(3.8)	3	3.88	0			
Tension headache								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	1	(0.6)	2	1.23	0			
>=30 - <35	0				0			
>=35	0				0			
Thrombotic stroke								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Transient ischaemic attack								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				1	(1.1)	1	1.07
Tremor								
<25	0				0			
>=25 - <30	2	(1.2)	3	1.85	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Trigeminal neuralgia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Vertebral artery occlusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Psychiatric disorders								
All								
<25	2	(2.3)	2	2.32	1	(1.3)	1	1.29
>=25 - <30	9	(5.5)	10	6.16	2	(1.2)	2	1.18
>=30 - <35	3	(1.9)	3	1.87	3	(2.1)	3	2.08

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(1.3)	1	1.29	4	(4.2)	4	4.29
Anxiety								
<25	0				1	(1.3)	1	1.29
>=25 - <30	3	(1.8)	3	1.85	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Bruxism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Depressed mood								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Depression								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Insomnia								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	4	(2.4)	4	2.46	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	2.15
Mood swings								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Nightmare								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Persistent depressive disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Sleep disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<25	2	(2.3)	4	4.65	2	(2.5)	2	2.59
>=25 - <30	2	(1.2)	2	1.23	7	(4.1)	9	5.29
>=30 - <35	7	(4.3)	9	5.62	10	(6.8)	10	6.92
>=35	3	(3.8)	3	3.88	1	(1.1)	1	1.07
Acute kidney injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Calculus urinary								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Chronic kidney disease								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Diabetic nephropathy								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Dysuria								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Haematuria								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				0			
Microalbuminuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Nephrolithiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nocturia								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Pollakiuria								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Pyelocaliectasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Renal colic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Renal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				0			
Renal impairment								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	2	1.18
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Ureterolithiasis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Urinary incontinence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Urinary retention								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Urinary tract obstruction								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Urine odour abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Reproductive system and breast disorders								
All								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	4	(2.4)	4	2.46	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	2	(1.4)	3	2.08
>=35	3	(3.8)	3	3.88	2	(2.1)	3	3.22
Atrophic vulvovaginitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Benign prostatic hyperplasia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Breast mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Breast pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Erectile dysfunction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	1	(1.3)	1	1.29	0			
Galactorrhoea								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Menopausal symptoms								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian cyst								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Penile rash								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	1.38
>=35	0				0			
Pruritus genital								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Uterine polyp								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Uterine prolapse								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvovaginal dryness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Vulvovaginal pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Respiratory, thoracic and mediastinal disorders								
All								
<25	9	(10.3)	15	17.43	6	(7.5)	6	7.76
>=25 - <30	8	(4.9)	9	5.54	15	(8.8)	24	14.11
>=30 - <35	23	(14.2)	27	16.87	13	(8.9)	18	12.46

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	5	(6.3)	8	10.34	4	(4.2)	4	4.29
Acquired diaphragmatic eventration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Acute pulmonary oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Acute respiratory failure								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Allergic bronchitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Asthma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	2	2.59	0			
Bronchiectasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Bronchitis chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Chronic obstructive pulmonary disease								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Cough								
<25	2	(2.3)	2	2.32	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	4	(2.3)	4	2.35
>=30 - <35	6	(3.7)	6	3.75	1	(0.7)	2	1.38
>=35	1	(1.3)	1	1.29	2	(2.1)	2	2.15

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspnoea								
<25	0				2	(2.5)	2	2.59
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				0			
Dyspnoea exertional								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Emphysema								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Epistaxis								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	1.18
>=30 - <35	0				0			
>=35	0				0			
Haemoptysis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Interstitial lung disease								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Laryngeal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Nasal congestion								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	2	(1.2)	2	1.25	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Nasal dryness								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nasal turbinate hypertrophy								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Oropharyngeal pain								
<25	5	(5.7)	5	5.81	3	(3.8)	3	3.88
>=25 - <30	1	(0.6)	1	0.62	2	(1.2)	3	1.76
>=30 - <35	3	(1.9)	4	2.50	2	(1.4)	2	1.38
>=35	1	(1.3)	1	1.29	0			
Paranasal sinus discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Pleural effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Pleuritic pain								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Productive cough								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Pulmonary embolism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Pulmonary fibrosis								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	0			
>=30 - <35	0				0			
>=35	0				0			
Pulmonary mass								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Respiratory disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	3	(2.1)	3	2.08

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Respiratory failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Rhinitis allergic								
<25	0				0			
>=25 - <30	0				1	(0.6)	5	2.94
>=30 - <35	0				0			
>=35	0				0			
Rhinorrhoea								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	3	(1.9)	3	1.87	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Sinus congestion								
<25	1	(1.1)	2	2.32	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Sinus pain								
<25	1	(1.1)	2	2.32	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sleep apnoea syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.87	0			
>=35	0				0			
Sneezing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Throat irritation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Upper-airway cough syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
<25	9	(10.3)	9	10.46	6	(7.5)	8	10.35
>=25 - <30	16	(9.8)	18	11.08	10	(5.8)	14	8.23
>=30 - <35	12	(7.4)	12	7.50	19	(13.0)	24	16.61
>=35	5	(6.3)	5	6.47	7	(7.4)	9	9.66
Actinic keratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Alopecia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				2	(1.4)	2	1.38
>=35	2	(2.5)	2	2.59	0			
Alopecia areata								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Angioedema								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Asteatosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Blister								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Cold sweat								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Cold urticaria								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Dermatitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	2	(1.4)	2	1.38
>=35	0				0			
Dermatitis allergic								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Dermatitis contact								
<25	0				0			
>=25 - <30	3	(1.8)	4	2.46	3	(1.8)	3	1.76
>=30 - <35	2	(1.2)	2	1.25	3	(2.1)	3	2.08
>=35	0				0			
Diabetic foot								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Drug eruption								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Dry skin								
<25	2	(2.3)	2	2.32	0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Ecchymosis								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Eczema								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	2	(1.2)	2	1.23	0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				1	(1.1)	1	1.07
Erythema								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Granuloma annulare								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Haemorrhage subcutaneous								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Hyperhidrosis								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Hyperkeratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Ingrowing nail								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Lentigo								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Lipodystrophy acquired								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Lipohypertrophy								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Macule								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Miliaria								
<25	0				2	(2.5)	2	2.59
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				1	(1.1)	1	1.07
Myxoid cyst								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Night sweats								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pruritus								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	1	(1.1)	1	1.07
Psoriasis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Purpura								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Rash								
<25	0				0			
>=25 - <30	2	(1.2)	2	1.23	2	(1.2)	2	1.18
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				2	(2.1)	2	2.15
Skin exfoliation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Skin fissures								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Skin lesion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Skin ulcer								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				2	(1.4)	2	1.38
>=35	0				1	(1.1)	1	1.07
Urticaria contact								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria thermal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	1	(1.3)	1	1.29	0			
Knee operation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Large intestinal polypectomy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Removal of foreign body								
<25	0				1	(1.3)	1	1.29
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vascular disorders								
All								
<25	4	(4.6)	4	4.65	3	(3.8)	3	3.88
>=25 - <30	12	(7.3)	15	9.23	12	(7.0)	15	8.82
>=30 - <35	10	(6.2)	11	6.87	7	(4.8)	7	4.84
>=35	6	(7.6)	7	9.05	3	(3.2)	4	4.29
Aortic arteriosclerosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Aortic stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Arteriosclerosis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood pressure inadequately controlled								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Brachiocephalic arteriosclerosis								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	1.18
>=30 - <35	1	(0.6)	1	0.62	1	(0.7)	1	0.69
>=35	0				0			
Flushing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Haematoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Hypertension								
<25	1	(1.1)	1	1.16	2	(2.5)	2	2.59
>=25 - <30	7	(4.3)	7	4.31	5	(2.9)	6	3.53
>=30 - <35	3	(1.9)	3	1.87	2	(1.4)	2	1.38
>=35	2	(2.5)	2	2.59	1	(1.1)	1	1.07
Hypertensive crisis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Hypertensive urgency								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Hypotension								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	1.25	0			
>=35	0				1	(1.1)	1	1.07
Iliac artery stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Intermittent claudication								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	1.07
Macroangiopathy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			
Peripheral arterial occlusive disease								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	1	(0.6)	1	0.59
>=30 - <35	0				1	(0.7)	1	0.69
>=35	0				0			
Peripheral artery occlusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Peripheral artery stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	2	1.23	0			
>=30 - <35	0				0			
>=35	0				0			
Peripheral coldness								
<25	1	(1.1)	1	1.16	1	(1.3)	1	1.29
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			
Peripheral vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Peripheral venous disease								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	1	(1.3)	1	1.29	0			
Superficial vein thrombosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.62	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thrombosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.62	0			
>=30 - <35	0				0			
>=35	0				0			
Varicose vein								
<25	1	(1.1)	1	1.16	0			
>=25 - <30	0				1	(0.6)	1	0.59
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_20221031_er
09NOV2022:10:11:25 - taesocptgrptrl/taesocptgrpbmisumontow1sas.txt

7.16.38 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	54				56			
>=25 - <30	92				104			
>=30 - <35	69				63			
>=35	47				40			
PYE (years)								
<25	31.79				31.52			
>=25 - <30	54.34				60.73			
>=30 - <35	40.99				37.01			
>=35	28.12				23.50			
Events								
<25	30	(55.6)	81	254.78	24	(42.9)	49	155.44
>=25 - <30	55	(59.8)	129	237.39	50	(48.1)	106	174.54
>=30 - <35	40	(58.0)	133	324.44	38	(60.3)	100	270.18
>=35	36	(76.6)	123	437.40	22	(55.0)	73	310.58
Blood and lymphatic system disorders								
All								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	3	7.32	0			
>=35	0				1	(2.5)	1	4.25
Anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	3	7.32	0			
>=35	0				0			
Thrombocytosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
<25	2	(3.7)	3	9.44	0			
>=25 - <30	2	(2.2)	3	5.52	2	(1.9)	2	3.29
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Acute myocardial infarction								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Atrial fibrillation								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Bradycardia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure congestive								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac flutter								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Coronary artery disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Myocardial infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Supraventricular tachycardia								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	2	(1.9)	2	3.29
>=30 - <35	0				0			
>=35	2	(4.3)	2	7.11	1	(2.5)	1	4.25
Deafness unilateral								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Ear pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Hypoacusis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tinnitus								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Vertigo								
<25	0				1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<25	0				2	(3.6)	2	6.34
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Adrenocortical insufficiency acute								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypothyroidism								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Inappropriate antidiuretic hormone secretion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Eye disorders								
All								
<25	6	(11.1)	7	22.02	4	(7.1)	5	15.86
>=25 - <30	10	(10.9)	11	20.24	10	(9.6)	12	19.76
>=30 - <35	6	(8.7)	6	14.64	7	(11.1)	7	18.91
>=35	5	(10.6)	7	24.89	4	(10.0)	6	25.53
Astigmatism								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Cataract								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	3	(2.9)	3	4.94
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				1	(2.5)	1	4.25
Cataract nuclear								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctival haemorrhage								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinal oedema								
<25	0				1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Diabetic retinopathy								
<25	2	(3.7)	2	6.29	3	(5.4)	3	9.52
>=25 - <30	3	(3.3)	3	5.52	5	(4.8)	5	8.23
>=30 - <35	2	(2.9)	2	4.88	5	(7.9)	5	13.51
>=35	3	(6.4)	4	14.22	3	(7.5)	4	17.02
Dry age-related macular degeneration								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Dry eye								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Epiretinal membrane								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Eye irritation								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Glaucoma								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Lacrimation increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Macular oedema								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Myopia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Non-proliferative retinopathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Ocular hyperaemia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Ocular hypertension								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Presbyopia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Retinal exudates								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Retinal vein occlusion								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Visual acuity reduced								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vitreous haemorrhage								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal disorders								
All								
<25	4	(7.4)	9	28.31	4	(7.1)	5	15.86
>=25 - <30	14	(15.2)	18	33.12	12	(11.5)	15	24.70
>=30 - <35	13	(18.8)	24	58.55	9	(14.3)	11	29.72
>=35	7	(14.9)	9	32.01	7	(17.5)	11	46.80
Abdominal pain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Abdominal pain lower								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Abdominal pain upper								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	3	7.32	2	(3.2)	2	5.40
>=35	0				0			
Chronic gastritis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Constipation								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	2	(2.2)	3	5.52	0			
>=30 - <35	1	(1.4)	3	7.32	0			
>=35	0				0			
Dental caries								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Diarrhoea								
<25	2	(3.7)	5	15.73	1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	3	(2.9)	3	4.94
>=30 - <35	6	(8.7)	6	14.64	2	(3.2)	2	5.40
>=35	4	(8.5)	4	14.22	3	(7.5)	3	12.76
Diverticulum								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Dyspepsia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	1	(2.1)	1	3.56	0			
Flatulence								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Food poisoning								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	2	3.29
>=30 - <35	0				0			
>=35	0				0			
Gastric dysplasia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Gastric mucosal hypertrophy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Gastric polyps								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Gastritis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal angiodysplasia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Gastrooesophageal reflux disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	2	(1.9)	2	3.29
>=30 - <35	0				0			
>=35	0				0			
Gingival bleeding								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Haemorrhoids								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	0				0			
Hiatus hernia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Hyperaesthesia teeth								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Intra-abdominal haematoma								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Large intestine polyp								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Nausea								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	2	(2.9)	2	4.88	2	(3.2)	2	5.40
>=35	2	(4.3)	2	7.11	3	(7.5)	3	12.76
Pancreatic pseudocyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Periodontal disease								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tongue rough								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Toothache								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				2	(5.0)	4	17.02
Vomiting								
<25	0				1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
General disorders and administration site conditions								
All								
<25	4	(7.4)	7	22.02	4	(7.1)	4	12.69
>=25 - <30	6	(6.5)	10	18.40	8	(7.7)	10	16.47
>=30 - <35	8	(11.6)	8	19.52	3	(4.8)	3	8.11
>=35	7	(14.9)	11	39.12	4	(10.0)	4	17.02
Asthenia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Chest discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(4.3)	2	7.11	0			
Chest pain								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Chills								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Condition aggravated								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Fatigue								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				1	(1.6)	1	2.70
>=35	2	(4.3)	3	10.67	1	(2.5)	1	4.25
Hunger								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Influenza like illness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Injection site reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	0				1	(2.5)	1	4.25
Injection site swelling								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Malaise								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				2	(1.9)	3	4.94
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Medical device site bruise								
<25	0				0			
>=25 - <30	1	(1.1)	2	3.68	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site dermatitis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site erythema								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site pruritus								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site rash								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Medical device site reaction								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Oedema peripheral								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	0				0			
Pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Pyrexia								
<25	2	(3.7)	2	6.29	2	(3.6)	2	6.34
>=25 - <30	2	(2.2)	2	3.68	2	(1.9)	2	3.29
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	2	(5.0)	2	8.51
Vaccination site pain								
<25	1	(1.9)	2	6.29	2	(3.6)	2	6.34
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Alcoholic liver disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Gallbladder polyp								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic cirrhosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	2	(3.2)	2	5.40
>=35	0				1	(2.5)	1	4.25
Allergy to arthropod bite								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Allergy to arthropod sting								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Anaphylactic reaction								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Seasonal allergy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	2	(3.2)	2	5.40
>=35	0				0			
Infections and infestations								
All								
<25	10	(18.5)	11	34.60	7	(12.5)	8	25.38
>=25 - <30	25	(27.2)	26	47.85	12	(11.5)	18	29.64
>=30 - <35	23	(33.3)	32	78.06	18	(28.6)	22	59.44
>=35	18	(38.3)	29	103.13	12	(30.0)	18	76.58
Abscess limb								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				1	(2.5)	1	4.25
Anal abscess								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Campylobacter gastroenteritis								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cellulitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	2	8.51
Conjunctivitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
COVID-19								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	5	(5.4)	5	9.20	0			
>=30 - <35	1	(1.4)	1	2.44	3	(4.8)	3	8.11
>=35	2	(4.3)	2	7.11	4	(10.0)	4	17.02
COVID-19 pneumonia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	0			
Cystitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	2	3.29
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Ear infection								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Enteritis infectious								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Folliculitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Fungal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	2	7.11	0			
Fungal skin infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Gastroenteritis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	4	(5.8)	4	9.76	0			
>=35	0				2	(5.0)	2	8.51
Gastrointestinal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Gingivitis								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Helicobacter infection								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Herpes zoster								
<25	0				0			
>=25 - <30	0				2	(1.9)	2	3.29
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Influenza								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				2	(3.2)	3	8.11
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Kidney infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Localised infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Nasopharyngitis								
<25	3	(5.6)	4	12.58	3	(5.4)	4	12.69
>=25 - <30	4	(4.3)	5	9.20	3	(2.9)	4	6.59
>=30 - <35	8	(11.6)	9	21.95	3	(4.8)	5	13.51
>=35	7	(14.9)	10	35.56	1	(2.5)	1	4.25
Onychomycosis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Otitis media								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				1	(2.5)	1	4.25
Paraspinal abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Peritonsillar abscess								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Pneumonia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulpitis dental								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Pustule								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Rhinitis								
<25	0				0			
>=25 - <30	0				1	(1.0)	3	4.94
>=30 - <35	0				0			
>=35	0				0			
Sinusitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	2	(1.9)	2	3.29
>=30 - <35	0				1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Soft tissue infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Subcutaneous abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Tinea pedis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Tinea versicolour								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Tonsillitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Tooth infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	2	4.88	1	(1.6)	1	2.70
>=35	0				2	(5.0)	2	8.51
Upper respiratory tract infection								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	3	(4.3)	4	9.76	1	(1.6)	1	2.70
>=35	3	(6.4)	5	17.78	2	(5.0)	2	8.51
Urinary tract infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	3	7.32	2	(3.2)	2	5.40
>=35	2	(4.3)	2	7.11	1	(2.5)	1	4.25
Vaginal infection								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Varicella zoster virus infection								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvitis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvovaginal candidiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Wound infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Injury, poisoning and procedural complications								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	5	(9.3)	6	18.87	4	(7.1)	4	12.69
>=25 - <30	8	(8.7)	11	20.24	7	(6.7)	7	11.53
>=30 - <35	8	(11.6)	10	24.39	8	(12.7)	12	32.42
>=35	6	(12.8)	12	42.67	3	(7.5)	3	12.76
Accidental overdose								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	3	(3.3)	3	5.52	0			
>=30 - <35	0				0			
>=35	0				0			
Arthropod bite								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				1	(2.5)	1	4.25
Arthropod sting								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Bone contusion								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Contusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	0				0			
Craniocerebral injury								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Face injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Facial bones fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Fall								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	2	(2.2)	2	3.68	1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Foot fracture								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Hand fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Heat illness								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Intentional overdose								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Joint injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	0				0			
Ligament sprain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Limb injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	2	5.40
>=35	0				0			
Muscle contusion								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Muscle injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Overdose								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(2.1)	1	3.56	0			
Rib fracture								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Road traffic accident								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Skin abrasion								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	0				0			
Skin laceration								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Stab wound								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Subcutaneous haematoma								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Tendon injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Tendon rupture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Thermal burn								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tibia fracture								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Underdose								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(3.2)	2	5.40
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Vaccination complication								
<25	0				2	(3.6)	2	6.34
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	2	(4.3)	6	21.34	0			
Wound								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Wrist fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	2	(1.9)	3	4.94
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	2	(4.3)	2	7.11	0			
Alanine aminotransferase increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Blood creatinine increased								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	2	(4.3)	2	7.11	0			
Blood potassium increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Intraocular pressure increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Liver function test abnormal								
<25	0				0			
>=25 - <30	0				1	(1.0)	2	3.29
>=30 - <35	0				0			
>=35	0				0			
SARS-CoV-2 test positive								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<25	1	(1.9)	1	3.15	2	(3.6)	6	19.03
>=25 - <30	2	(2.2)	2	3.68	4	(3.8)	5	8.23
>=30 - <35	3	(4.3)	3	7.32	4	(6.3)	4	10.81
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Abnormal weight gain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Hyperammonaemia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Hypercholesterolaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Hyperglycaemia								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Hyperkalaemia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Hyperlipidaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				3	(4.8)	3	8.11
>=35	1	(2.1)	1	3.56	0			
Hyperuricaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Hypoglycaemia								
<25	0				1	(1.8)	5	15.86
>=25 - <30	1	(1.1)	1	1.84	2	(1.9)	3	4.94
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders								
All								
<25	7	(13.0)	15	47.18	6	(10.7)	6	19.03
>=25 - <30	9	(9.8)	14	25.76	6	(5.8)	7	11.53
>=30 - <35	10	(14.5)	17	41.47	10	(15.9)	17	45.93
>=35	12	(25.5)	14	49.79	7	(17.5)	15	63.82
Arthralgia								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	3	(3.3)	4	7.36	1	(1.0)	1	1.65
>=30 - <35	2	(2.9)	2	4.88	4	(6.3)	6	16.21
>=35	0				4	(10.0)	5	21.27
Arthritis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Axillary mass								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Back pain								
<25	0				2	(3.6)	2	6.34
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	3	(4.3)	3	7.32	6	(9.5)	7	18.91
>=35	2	(4.3)	2	7.11	3	(7.5)	4	17.02
Bursitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Flank pain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Intervertebral disc disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Intervertebral disc protrusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle spasms								
<25	4	(7.4)	6	18.87	1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	3	(6.4)	3	10.67	0			
Musculoskeletal stiffness								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Myalgia								
<25	1	(1.9)	1	3.15	2	(3.6)	2	6.34
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	0			
Neck pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	0			
Osteoarthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Osteoporosis								
<25	0				0			
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	0				0			
>=35	0				0			
Pain in extremity								
<25	0				0			
>=25 - <30	0				3	(2.9)	4	6.59
>=30 - <35	0				1	(1.6)	1	2.70
>=35	3	(6.4)	3	10.67	1	(2.5)	1	4.25
Periarthritis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Plantar fasciitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Polymyalgia rheumatica								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	3	12.76
Rheumatoid arthritis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Rotator cuff syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Soft tissue swelling								
<25	1	(1.9)	3	9.44	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Spinal stenosis								
<25	1	(1.9)	2	6.29	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	2	4.88	0			
>=35	0				0			
Tendonitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	4	9.76	0			
>=35	0				0			
Tenosynovitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Trigger finger								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	3	(2.9)	3	4.94
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Breast cancer								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Chronic myeloid leukaemia								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Colon adenoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Colon cancer stage II								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Gastric cancer								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Lymphangioma								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Pancreatic carcinoma metastatic								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nervous system disorders								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	4	(7.4)	5	15.73	2	(3.6)	3	9.52
>=25 - <30	6	(6.5)	10	18.40	10	(9.6)	12	19.76
>=30 - <35	7	(10.1)	11	26.83	7	(11.1)	10	27.02
>=35	10	(21.3)	16	56.90	6	(15.0)	9	38.29
Autonomic nervous system imbalance								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Burning sensation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Carotid artery aneurysm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Carpal tunnel syndrome								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cerebral infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Cervicobrachial syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Diabetic neuropathy								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dizziness								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	4	(3.8)	5	8.23
>=30 - <35	0				3	(4.8)	4	10.81
>=35	2	(4.3)	3	10.67	1	(2.5)	3	12.76

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Facial paralysis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Headache								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	2	(2.2)	2	3.68	4	(3.8)	4	6.59
>=30 - <35	4	(5.8)	7	17.08	3	(4.8)	4	10.81
>=35	7	(14.9)	10	35.56	2	(5.0)	2	8.51
Hypoaesthesia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Migraine								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Neuralgia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Neuropathy peripheral								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Peripheral paralysis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Piriformis syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Post herpetic neuralgia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Restless legs syndrome								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Sciatica								
<25	0				1	(1.8)	1	3.17
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	1	(2.5)	1	4.25
Somnolence								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Syncope								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Tension headache								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Thalamic infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Thrombotic stroke								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Tremor								
<25	0				0			
>=25 - <30	0				2	(1.9)	2	3.29
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<25	1	(1.9)	2	6.29	1	(1.8)	1	3.17
>=25 - <30	2	(2.2)	2	3.68	2	(1.9)	2	3.29
>=30 - <35	0				2	(3.2)	2	5.40
>=35	1	(2.1)	1	3.56	0			
Adjustment disorder								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Depression								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				2	(3.2)	2	5.40
>=35	0				0			
Insomnia								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Major depression								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Sleep disorder								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Renal and urinary disorders								
All								
<25	1	(1.9)	3	9.44	0			
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	4	(5.8)	4	9.76	0			
>=35	1	(2.1)	1	3.56	0			
Bladder prolapse								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic nephropathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Hydronephrosis								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nephrotic syndrome								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Pollakiuria								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Polyuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Renal cyst								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Renal impairment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Urethral stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Urine odour abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<25	2	(3.7)	2	6.29	0			
>=25 - <30	0				2	(1.9)	2	3.29
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	0				0			
Benign prostatic hyperplasia								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cervical polyp								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Erectile dysfunction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Prostatitis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Pruritus genital								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	0				0			
>=35	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	6	(6.5)	8	14.72	1	(1.0)	2	3.29
>=30 - <35	3	(4.3)	5	12.20	2	(3.2)	2	5.40
>=35	5	(10.6)	15	53.34	1	(2.5)	1	4.25
Acute respiratory failure								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chronic obstructive pulmonary disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.9)	2	4.88	0			
>=35	0				0			
Cough								
<25	0				0			
>=25 - <30	1	(1.1)	2	3.68	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Epistaxis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	3	(6.4)	7	24.89	0			
Nasal congestion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Nasal obstruction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Nasal septum deviation								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Oropharyngeal pain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	1	(1.0)	2	3.29
>=30 - <35	0				0			
>=35	0				1	(2.5)	1	4.25
Productive cough								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	0			
Respiratory failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinorrhoea								
<25	0				0			
>=25 - <30	3	(3.3)	3	5.52	0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	2	(4.3)	4	14.22	0			
Sleep apnoea syndrome								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Sneezing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Skin and subcutaneous tissue disorders								
All								
<25	3	(5.6)	4	12.58	2	(3.6)	2	6.34
>=25 - <30	5	(5.4)	5	9.20	1	(1.0)	1	1.65
>=30 - <35	3	(4.3)	3	7.32	3	(4.8)	3	8.11
>=35	2	(4.3)	2	7.11	0			
Alopecia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Blister								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	0				0			
Dermal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Dermatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Eczema								
<25	1	(1.9)	1	3.15	1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hyperhidrosis								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	0				0			
Miliaria								
<25	2	(3.7)	2	6.29	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Neurodermatitis								
<25	0				1	(1.8)	1	3.17
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pruritus								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Rash								
<25	1	(1.9)	1	3.15	0			
>=25 - <30	0				1	(1.0)	1	1.65
>=30 - <35	1	(1.4)	1	2.44	0			
>=35	1	(2.1)	1	3.56	0			
Rash papular								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria								
<25	0				0			
>=25 - <30	2	(2.2)	2	3.68	0			
>=30 - <35	0				0			
>=35	1	(2.1)	1	3.56	0			
Surgical and medical procedures								
All								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			
Toe amputation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.6)	1	2.70
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
<25	0				0			
>=25 - <30	3	(3.3)	3	5.52	2	(1.9)	2	3.29
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	2	(5.0)	2	8.51
Hypertension								
<25	0				0			
>=25 - <30	2	(2.2)	2	3.68	2	(1.9)	2	3.29
>=30 - <35	1	(1.4)	1	2.44	1	(1.6)	1	2.70
>=35	1	(2.1)	1	3.56	2	(5.0)	2	8.51
Orthostatic hypotension								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.84	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

7.16.39 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	42				49			
>=25 - <30	95				96			
>=30 - <35	93				99			
>=35	61				47			
PYE (years)								
<25	23.95				28.37			
>=25 - <30	55.61				54.86			
>=30 - <35	53.13				56.58			
>=35	34.67				26.99			
Events								
<25	19	(45.2)	49	204.61	26	(53.1)	71	250.27
>=25 - <30	48	(50.5)	116	208.60	52	(54.2)	163	297.13
>=30 - <35	62	(66.7)	182	342.55	62	(62.6)	198	349.96
>=35	42	(68.9)	108	311.46	27	(57.4)	118	437.16

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
<25	1	(2.4)	1	4.18	2	(4.1)	2	7.05
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	2	(3.3)	2	5.77	2	(4.3)	2	7.41
Anaemia								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	2	(4.3)	2	7.41
Blood loss anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Eosinophilia								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Iron deficiency anaemia								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lymphadenopathy mediastinal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Cardiac disorders								
All								
<25	0				2	(4.1)	3	10.57
>=25 - <30	1	(1.1)	2	3.60	4	(4.2)	4	7.29
>=30 - <35	4	(4.3)	4	7.53	5	(5.1)	9	15.91
>=35	2	(3.3)	2	5.77	3	(6.4)	6	22.23
Acute myocardial infarction								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina pectoris								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Aortic valve calcification								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Aortic valve sclerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Atrial enlargement								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Atrial fibrillation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Bundle branch block left								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Bundle branch block right								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	2	7.41
Cardiac failure congestive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(2.0)	3	5.30
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac perfusion defect								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	2	3.53
>=35	0				0			
Coronary artery disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				2	(4.3)	2	7.41
Left atrial enlargement								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Left ventricular hypertrophy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Myocardial infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Myocardial ischaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Palpitations								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Pericarditis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sinus bradycardia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tachycardia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Congenital, familial and genetic disorders								
All								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Corneal dystrophy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Ear and labyrinth disorders								
All								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				4	(4.0)	4	7.07
>=35	0				0			
Cerumen impaction								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Ear discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Middle ear inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Vertigo								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Adrenocortical insufficiency acute								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Hypogonadism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Hypothyroidism								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Eye disorders								
All								
<25	2	(4.8)	3	12.53	4	(8.2)	4	14.10
>=25 - <30	11	(11.6)	13	23.38	11	(11.5)	17	30.99
>=30 - <35	7	(7.5)	9	16.94	13	(13.1)	23	40.65
>=35	6	(9.8)	8	23.07	10	(21.3)	13	48.16
Age-related macular degeneration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Astigmatism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Cataract								
<25	0				1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	2	3.65
>=30 - <35	0				1	(1.0)	2	3.53
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Corneal erosion								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinal oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	2	(4.3)	3	11.11
Diabetic retinopathy								
<25	2	(4.8)	3	12.53	0			
>=25 - <30	6	(6.3)	7	12.59	8	(8.3)	8	14.58
>=30 - <35	2	(2.2)	2	3.76	3	(3.0)	3	5.30
>=35	2	(3.3)	2	5.77	4	(8.5)	4	14.82
Diplopia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Eye discharge								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Eye inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Eye pain								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Macular degeneration								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Macular oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	2	(3.3)	2	5.77	1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Meibomianitis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Open angle glaucoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	2	3.53
>=35	0				0			
Presbyopia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Retinal deposits								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal detachment								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Retinal drusen								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Retinal exudates								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Retinal haemorrhage								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal scar								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Retinopathy hypertensive								
<25	0				1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				2	(2.0)	2	3.53
>=35	1	(1.6)	1	2.88	0			
Vision blurred								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Visual impairment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	9	15.91
>=35	0				0			
Vitreous detachment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Vitreous haemorrhage								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Gastrointestinal disorders								
All								
<25	4	(9.5)	4	16.70	6	(12.2)	10	35.25
>=25 - <30	12	(12.6)	21	37.76	12	(12.5)	14	25.52
>=30 - <35	13	(14.0)	17	32.00	11	(11.1)	18	31.81
>=35	6	(9.8)	8	23.07	6	(12.8)	7	25.93
Abdominal discomfort								
<25	0				1	(2.0)	2	7.05
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Abdominal distension								
<25	0				0			
>=25 - <30	0				2	(2.1)	2	3.65
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Abdominal pain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	2	(2.1)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	2	(2.0)	3	5.30
>=35	0				1	(2.1)	1	3.70
Abdominal pain upper								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Chronic gastritis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	0				0			
Constipation								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Dental caries								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				2	(2.1)	2	3.65
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Diarrhoea								
<25	2	(4.8)	2	8.35	0			
>=25 - <30	5	(5.3)	6	10.79	5	(5.2)	5	9.11
>=30 - <35	4	(4.3)	6	11.29	3	(3.0)	3	5.30
>=35	4	(6.6)	4	11.54	1	(2.1)	1	3.70
Eructation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Faeces pale								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Food poisoning								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Gastrointestinal disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(2.1)	1	3.70
Gastrointestinal haemorrhage								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastrooesophageal reflux disease								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Gingival disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Hypoaesthesia oral								
<25	0				0			
>=25 - <30	2	(2.1)	4	7.19	0			
>=30 - <35	0				0			
>=35	0				0			
Nausea								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	2	(2.2)	2	3.76	4	(4.0)	4	7.07
>=35	1	(1.6)	1	2.88	0			
Pancreatic duct dilatation								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pancreatic failure								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pancreatitis chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Periodontal disease								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Proctalgia								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Toothache								
<25	0				1	(2.0)	2	7.05
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Upper gastrointestinal haemorrhage								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vomiting								
<25	0				0			
>=25 - <30	3	(3.2)	5	8.99	0			
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	2	3.53
>=35	2	(3.3)	2	5.77	0			
General disorders and administration site conditions								
All								
<25	3	(7.1)	5	20.88	4	(8.2)	11	38.77
>=25 - <30	5	(5.3)	7	12.59	6	(6.3)	7	12.76
>=30 - <35	13	(14.0)	20	37.64	12	(12.1)	14	24.74
>=35	5	(8.2)	6	17.30	4	(8.5)	4	14.82
Asthenia								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Axillary pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Chest pain								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Discomfort								
<25	0				1	(2.0)	8	28.20

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Facial pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Fatigue								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(3.2)	4	7.53	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Feeling abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	0				0			
Inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Injection site pain								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Injection site rash								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Injection site reaction								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Malaise								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Medical device site dermatitis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site erythema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Medical device site pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Medical device site reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Multiple organ dysfunction syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Oedema								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Oedema due to renal disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Oedema peripheral								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	3	5.65	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Peripheral swelling								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	0				0			
Pyrexia								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	2	(2.1)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	2	(2.0)	3	5.30

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(2.1)	1	3.70
Thirst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Vaccination site inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Vaccination site pain								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Vaccination site pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Xerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<25	1	(2.4)	1	4.18	2	(4.1)	4	14.10
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	2	3.76	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Biliary dyskinesia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Cholecystitis chronic								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Gallbladder polyp								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic function abnormal								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic steatosis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatomegaly								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Hyperplastic cholecystopathy								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Liver disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	2	3.53
>=35	0				0			
Drug hypersensitivity								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Hypersensitivity								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Seasonal allergy								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	0				0			
Infections and infestations								
All								
<25	6	(14.3)	10	41.76	8	(16.3)	9	31.72
>=25 - <30	20	(21.1)	27	48.55	29	(30.2)	45	82.03
>=30 - <35	36	(38.7)	52	97.87	27	(27.3)	43	76.00
>=35	25	(41.0)	28	80.75	15	(31.9)	23	85.21
Abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Asymptomatic COVID-19								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Bacteraemia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Breast abscess								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Bronchitis								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	3	(3.2)	3	5.39	1	(1.0)	1	1.82
>=30 - <35	3	(3.2)	3	5.65	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Candida infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Cellulitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Cholecystitis infective								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Conjunctivitis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Coronavirus infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	2	7.41
COVID-19								
<25	2	(4.8)	2	8.35	1	(2.0)	1	3.52
>=25 - <30	5	(5.3)	5	8.99	7	(7.3)	8	14.58
>=30 - <35	10	(10.8)	10	18.82	11	(11.1)	11	19.44
>=35	9	(14.8)	9	25.96	4	(8.5)	5	18.52
COVID-19 pneumonia								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	2	(3.3)	2	5.77	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
<25	0				0			
>=25 - <30	0				2	(2.1)	2	3.65
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77
>=35	0				0			
Diabetic foot infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Eye infection								
<25	0				0			
>=25 - <30	0				2	(2.1)	2	3.65
>=30 - <35	0				0			
>=35	0				0			
Fungal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Fungal skin infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Gastroenteritis								
<25	0				0			
>=25 - <30	3	(3.2)	3	5.39	3	(3.1)	4	7.29
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	2	3.53
>=35	2	(3.3)	2	5.77	0			
Gastroenteritis viral								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Gingivitis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Herpes zoster								
<25	0				1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infected dermal cyst								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Influenza								
<25	0				0			
>=25 - <30	0				5	(5.2)	7	12.76
>=30 - <35	5	(5.4)	5	9.41	1	(1.0)	1	1.77
>=35	0				2	(4.3)	2	7.41
Laryngitis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Localised infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Nasopharyngitis								
<25	0				3	(6.1)	3	10.57
>=25 - <30	3	(3.2)	3	5.39	2	(2.1)	2	3.65
>=30 - <35	5	(5.4)	5	9.41	5	(5.1)	7	12.37
>=35	0				2	(4.3)	3	11.11
Oral herpes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	2	3.76	0			
>=35	0				0			
Osteomyelitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Otitis media								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Otitis media acute								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paronychia								
<25	0				0			
>=25 - <30	0				1	(1.0)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Periodontitis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Pharyngitis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				3	(3.1)	3	5.47
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	2	3.53
>=35	0				1	(2.1)	1	3.70
Pharyngotonsillitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Pneumonia								
<25	2	(4.8)	2	8.35	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Pneumonia viral								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Post procedural infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Pulmonary tuberculoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Pulpitis dental								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory syncytial virus infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Respiratory tract infection								
<25	0				1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	2	(3.3)	2	5.77	0			
Respiratory tract infection viral								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	2	3.76	2	(2.0)	2	3.53
>=35	3	(4.9)	3	8.65	2	(4.3)	3	11.11
Sepsis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Sinusitis								
<25	0				0			
>=25 - <30	1	(1.1)	2	3.60	0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	2	(3.3)	2	5.77	0			
Soft tissue infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Tooth abscess								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				1	(2.1)	2	7.41
Tooth infection								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Upper respiratory tract infection								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				4	(4.2)	4	7.29
>=30 - <35	3	(3.2)	3	5.65	1	(1.0)	1	1.77
>=35	2	(3.3)	2	5.77	1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urinary tract infection								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	2	(2.1)	3	5.47
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	3	5.30
>=35	0				1	(2.1)	1	3.70
Viral infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Viral rhinitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Viral tracheitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Vulvovaginal mycotic infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Injury, poisoning and procedural complications								
All								
<25	1	(2.4)	1	4.18	3	(6.1)	4	14.10
>=25 - <30	3	(3.2)	3	5.39	8	(8.3)	11	20.05
>=30 - <35	10	(10.8)	14	26.35	11	(11.1)	15	26.51
>=35	5	(8.2)	7	20.19	5	(10.6)	5	18.52
Accidental overdose								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	2	3.53
>=35	0				0			
Accidental underdose								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Animal bite								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthropod bite								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Arthropod sting								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Chillblains								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Concussion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	0				0			
Contusion								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Crush injury								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Exposure to SARS-CoV-2								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Extra dose administered								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Fall								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Foot fracture								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Incorrect dose administered								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	2	3.53
>=35	1	(1.6)	1	2.88	0			
Joint injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Ligament sprain								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Limb injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Medication error								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Meniscus injury								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Muscle injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Muscle strain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Overdose								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Product administration error								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Skin abrasion								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	2	(2.1)	2	3.65
>=30 - <35	0				0			
>=35	0				0			
Skin laceration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Spinal column injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Spinal compression fracture								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Subcutaneous haematoma								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Subdural haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Thermal burn								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Tooth fracture								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Vaccination complication								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				2	(2.0)	2	3.53
>=35	0				1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Wound								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Wrong product administered								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	2	3.76	0			
>=35	0				1	(2.1)	1	3.70
Investigations								
All								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	4	(4.2)	5	9.11
>=30 - <35	3	(3.2)	3	5.65	3	(3.0)	3	5.30
>=35	7	(11.5)	10	28.84	5	(10.6)	5	18.52
Amylase increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Blood alkaline phosphatase increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Blood creatinine increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Blood pressure increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Blood triglycerides increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Blood urine present								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Catheterisation cardiac								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Electrocardiogram T wave inversion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Eosinophil count increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Glomerular filtration rate decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Haematocrit increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Haemoglobin increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Liver function test abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Liver function test increased								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Platelet count decreased								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
SARS-CoV-2 test positive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Transaminases increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Weight increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77
>=35	4	(6.6)	4	11.54	2	(4.3)	2	7.41
Metabolism and nutrition disorders								
All								
<25	3	(7.1)	4	16.70	3	(6.1)	3	10.57
>=25 - <30	5	(5.3)	5	8.99	8	(8.3)	8	14.58
>=30 - <35	6	(6.5)	7	13.18	4	(4.0)	5	8.84
>=35	1	(1.6)	2	5.77	5	(10.6)	6	22.23
Decreased appetite								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Dehydration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Dyslipidaemia								
<25	3	(7.1)	4	16.70	2	(4.1)	2	7.05
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Fluid retention								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Hypercholesterolaemia								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperglycaemia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				3	(6.4)	3	11.11
Hyperkalaemia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	3	(3.1)	3	5.47
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Hypertriglyceridaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Hypoalbuminaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Hypoglycaemia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	2	(2.1)	2	3.65
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	0				0			
Hypokalaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Hyponatraemia								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Increased appetite								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Lipomatosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Vitamin D deficiency								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Musculoskeletal and connective tissue disorders								
All								
<25	7	(16.7)	8	33.41	4	(8.2)	7	24.67
>=25 - <30	4	(4.2)	4	7.19	9	(9.4)	11	20.05
>=30 - <35	13	(14.0)	18	33.88	9	(9.1)	12	21.21
>=35	8	(13.1)	11	31.72	13	(27.7)	18	66.69
Arthralgia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	2	(2.2)	2	3.76	4	(4.0)	4	7.07
>=35	3	(4.9)	4	11.54	1	(2.1)	1	3.70
Arthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Back disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Back pain								
<25	4	(9.5)	4	16.70	1	(2.0)	1	3.52
>=25 - <30	0				6	(6.3)	6	10.94
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77
>=35	2	(3.3)	2	5.77	3	(6.4)	3	11.11
Bone cyst								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Bone pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Coccydynia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Flank pain								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Foot deformity								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Intervertebral disc protrusion								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Jaw disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Muscle spasms								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Myalgia								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	0				0			
Myositis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Neck pain								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	3	(3.2)	3	5.65	0			
>=35	0				1	(2.1)	1	3.70
Osteoarthritis								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	2	(2.1)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	2	(2.0)	3	5.30
>=35	2	(3.3)	2	5.77	3	(6.4)	3	11.11
Osteochondrosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				2	(4.3)	2	7.41
Pain in extremity								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				1	(2.0)	2	7.05
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				1	(2.1)	1	3.70
Periarthritis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Periostitis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Rotator cuff syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Spinal osteoarthritis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Tendon disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Tendonitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Tenosynovitis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Torticollis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Trigger finger								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	2	(2.1)	2	3.60	0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	0				0			
>=25 - <30	3	(3.2)	3	5.39	0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	3	(6.4)	5	18.52
Adrenal adenoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Eye naevus								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Lung adenocarcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Osteoma								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Pancreatic neoplasm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Small cell lung cancer								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Small intestine neuroendocrine tumour								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Uterine cancer								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Uterine leiomyoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Nervous system disorders								
All								
<25	4	(9.5)	6	25.05	3	(6.1)	4	14.10
>=25 - <30	6	(6.3)	11	19.78	13	(13.5)	20	36.46
>=30 - <35	5	(5.4)	6	11.29	9	(9.1)	18	31.81
>=35	4	(6.6)	9	25.96	4	(8.5)	5	18.52
Anosmia								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Basilar migraine								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Carpal tunnel syndrome								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				2	(2.1)	2	3.65
>=30 - <35	1	(1.1)	1	1.88	2	(2.0)	2	3.53
>=35	0				0			
Cerebral arteriosclerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Cerebrovascular accident								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Cerebrovascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Cognitive disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic neuropathy								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Dizziness								
<25	1	(2.4)	2	8.35	0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	2	3.53
>=35	1	(1.6)	4	11.54	0			
Dizziness postural								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Dysgeusia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Essential tremor								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Facial nerve disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Headache								
<25	2	(4.8)	3	12.53	2	(4.1)	3	10.57
>=25 - <30	2	(2.1)	3	5.39	4	(4.2)	5	9.11
>=30 - <35	3	(3.2)	3	5.65	2	(2.0)	3	5.30
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Hemiparesis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Hypoaesthesia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Hypoglycaemic coma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Hyporeflexia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Memory impairment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Migraine								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Morton's neuralgia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Neuropathy peripheral								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Paraesthesia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				2	(4.3)	2	7.41
Sciatica								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Sleep deficit								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Transient ischaemic attack								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Tremor								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	4	7.29
>=30 - <35	0				1	(1.0)	2	3.53
>=35	0				0			
Vascular encephalopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	6	(6.1)	6	10.60
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Affect lability								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Depression								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	2	(2.0)	2	3.53
>=35	0				0			
Fear								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Insomnia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Mental status changes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Mixed anxiety and depressive disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Phobia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Sleep disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	2	(2.1)	4	7.19	3	(3.1)	3	5.47
>=30 - <35	1	(1.1)	2	3.76	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Acute kidney injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Chronic kidney disease								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Dysuria								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Haematuria								
<25	0				0			
>=25 - <30	1	(1.1)	2	3.60	0			
>=30 - <35	0				0			
>=35	0				0			
Hydrocalyx								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Nephropathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Renal colic								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Renal cyst								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Benign prostatic hyperplasia								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Menopausal disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
<25	2	(4.8)	2	8.35	4	(8.2)	4	14.10
>=25 - <30	3	(3.2)	3	5.39	5	(5.2)	6	10.94
>=30 - <35	6	(6.5)	8	15.06	7	(7.1)	10	17.67
>=35	6	(9.8)	7	20.19	3	(6.4)	3	11.11
Asthma								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	0			
Bronchitis chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Cough								
<25	0				2	(4.1)	2	7.05
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	2	(2.0)	2	3.53
>=35	1	(1.6)	1	2.88	0			
Dyspnoea								
<25	0				1	(2.0)	1	3.52
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				3	(3.0)	4	7.07
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Emphysema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Epistaxis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				1	(1.0)	2	3.65
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Nasal congestion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Nasal septum deviation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Oropharyngeal pain								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				0			
Paranasal cyst								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Pleurisy								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Pulmonary fibrosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Pulmonary hypertension								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory disorder								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	1	(1.6)	1	2.88	2	(4.3)	2	7.41
Rhinitis allergic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Rhinorrhoea								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sinus congestion								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Sinus pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Skin and subcutaneous tissue disorders								
All								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	5	(5.3)	5	8.99	3	(3.1)	3	5.47
>=30 - <35	4	(4.3)	4	7.53	6	(6.1)	7	12.37
>=35	2	(3.3)	3	8.65	5	(10.6)	5	18.52
Alopecia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Blister								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Cold sweat								
<25	0				0			
>=25 - <30	2	(2.1)	2	3.60	1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis contact								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Eczema								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	1	(1.0)	1	1.82
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Hyperhidrosis								
<25	1	(2.4)	1	4.18	1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Hyperkeratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Intertrigo								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Lipohypertrophy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	1.82
>=30 - <35	0				0			
>=35	0				0			
Pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(2.0)	2	3.53
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Rash								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	1	(2.1)	1	3.70
Seborrhoea								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Skin ulcer								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	1	(1.1)	1	1.88	1	(1.0)	1	1.77
>=35	0				1	(2.1)	1	3.70
Umbilical haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Urticaria								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			
>=30 - <35	0				0			
>=35	0				0			
Surgical and medical procedures								
All								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(2.2)	2	3.76	1	(1.0)	1	1.77

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Cardiac pacemaker replacement								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Shoulder operation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Tooth extraction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Vascular disorders								
All								
<25	1	(2.4)	1	4.18	1	(2.0)	2	7.05
>=25 - <30	1	(1.1)	1	1.80	4	(4.2)	4	7.29
>=30 - <35	3	(3.2)	7	13.18	6	(6.1)	6	10.60
>=35	3	(4.9)	3	8.65	5	(10.6)	7	25.93
Aortic arteriosclerosis								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Arteriosclerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	1	3.70
Blood pressure fluctuation								
<25	0				1	(2.0)	1	3.52
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Deep vein thrombosis								
<25	0				0			
>=25 - <30	1	(1.1)	1	1.80	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Diabetic vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	1	(1.6)	1	2.88	0			
Hypertension								
<25	0				0			
>=25 - <30	0				4	(4.2)	4	7.29
>=30 - <35	2	(2.2)	2	3.76	0			
>=35	0				2	(4.3)	2	7.41
Hypertensive crisis								
<25	1	(2.4)	1	4.18	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(2.1)	3	11.11
Hypertensive urgency								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Hypotension								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Neovascularisation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			
Orthostatic hypotension								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral arterial occlusive disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	1	1.88	0			
>=35	0				0			
Peripheral artery stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(1.1)	3	5.65	0			
>=35	0				0			
Peripheral venous disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.6)	1	2.88	0			
Thrombophlebitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(1.0)	1	1.77
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_20221031_er
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7.16.40 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	105				135			
>=25 - <30	118				102			
>=30 - <35	46				41			
>=35	21				14			
PYE (years)								
<25	50.77				67.45			
>=25 - <30	58.04				49.72			
>=30 - <35	23.14				19.93			
>=35	10.36				7.01			
Events								
<25	56	(53.3)	153	301.35	83	(61.5)	345	511.47
>=25 - <30	83	(70.3)	217	373.88	72	(70.6)	183	368.05
>=30 - <35	36	(78.3)	106	458.08	27	(65.9)	71	356.22
>=35	14	(66.7)	31	299.31	8	(57.1)	20	285.13

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			
Anaemia								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Iron deficiency anaemia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Lymphadenitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Lymphadenopathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Thrombocytopenia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Cardiac disorders								
All								
<25	3	(2.9)	3	5.91	3	(2.2)	3	4.45
>=25 - <30	4	(3.4)	4	6.89	1	(1.0)	1	2.01
>=30 - <35	2	(4.3)	2	8.64	1	(2.4)	2	10.03
>=35	0				0			
Angina pectoris								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina unstable								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Atrial fibrillation								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Bundle branch block right								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Cardiomegaly								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiovascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Myocardial ischaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Palpitations								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Ventricular extrasystoles								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<25	2	(1.9)	2	3.94	2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Deafness neurosensory								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ear pain								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vertigo								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Endocrine disorders								
All								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypothyroidism								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Eye disorders								
All								
<25	11	(10.5)	13	25.61	16	(11.9)	20	29.65
>=25 - <30	12	(10.2)	17	29.29	6	(5.9)	10	20.11
>=30 - <35	4	(8.7)	5	21.61	4	(9.8)	5	25.09
>=35	2	(9.5)	2	19.31	2	(14.3)	2	28.51

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerotic retinopathy								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Astigmatism								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Cataract								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			
Cataract nuclear								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Conjunctival haemorrhage								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Corneal erosion								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinal oedema								
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinopathy								
<25	6	(5.7)	6	11.82	7	(5.2)	7	10.38
>=25 - <30	6	(5.1)	6	10.34	3	(2.9)	3	6.03
>=30 - <35	0				3	(7.3)	3	15.05
>=35	0				1	(7.1)	1	14.26
Dry eye								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epiretinal membrane								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Glaucoma								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				1	(7.1)	1	14.26
Macular oedema								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	2	(4.3)	3	12.96	0			
>=35	0				0			
Myopia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Non-proliferative retinopathy								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(9.5)	2	19.31	0			
Ocular hypertension								
<25	0				1	(0.7)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Photopsia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Posterior capsule opacification								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Presbyopia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pterygium								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Retinal vascular disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Retinopathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Retinopathy hypertensive								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vision blurred								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vitreous detachment								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vitreous floaters								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal disorders								
All								
<25	8	(7.6)	9	17.73	12	(8.9)	21	31.13
>=25 - <30	7	(5.9)	9	15.51	6	(5.9)	11	22.12
>=30 - <35	9	(19.6)	17	73.46	3	(7.3)	4	20.07
>=35	2	(9.5)	3	28.97	3	(21.4)	5	71.28
Abdominal discomfort								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(7.1)	1	14.26
Abdominal distension								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Abdominal pain								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Abdominal pain upper								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	0				0			
Anal fissure								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Chronic gastritis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Constipation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Dental caries								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diarrhoea								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	3	(6.5)	4	17.29	0			
>=35	1	(4.8)	1	9.66	2	(14.3)	3	42.77
Diverticulum intestinal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspepsia								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Faeces soft								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastric polyps								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Gastritis								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastritis erosive								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Gastrooesophageal reflux disease								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gingival recession								
<25	0				1	(0.7)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Haemorrhoids								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hiatus hernia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Impaired gastric emptying								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	2	8.64	0			
>=35	0				0			
Irritable bowel syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Lumbar hernia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nausea								
<25	0				4	(3.0)	4	5.93
>=25 - <30	0				3	(2.9)	3	6.03
>=30 - <35	3	(6.5)	3	12.96	0			
>=35	1	(4.8)	1	9.66	1	(7.1)	1	14.26
Odynophagia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pancreatic failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Pneumatosis intestinalis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Toothache								
<25	1	(1.0)	1	1.97	2	(1.5)	3	4.45
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	2	10.03
>=35	0				0			
Vomiting								
<25	1	(1.0)	1	1.97	3	(2.2)	3	4.45
>=25 - <30	4	(3.4)	4	6.89	1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	1	(4.8)	1	9.66	0			
General disorders and administration site conditions								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	12	(11.4)	12	23.64	16	(11.9)	55	81.54
>=25 - <30	17	(14.4)	26	44.80	13	(12.7)	20	40.22
>=30 - <35	9	(19.6)	9	38.89	3	(7.3)	6	30.10
>=35	3	(14.3)	3	28.97	2	(14.3)	2	28.51
Asthenia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Chest pain								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	14.26
Fatigue								
<25	0				0			
>=25 - <30	2	(1.7)	3	5.17	1	(1.0)	1	2.01
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	1	(4.8)	1	9.66	0			
Hunger								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	2	10.03
>=35	0				0			
Hyperthermia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Influenza like illness								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	2	(1.7)	2	3.45	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Injection site mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Injection site pain								
<25	0				1	(0.7)	1	1.48

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Injection site urticaria								
<25	0				0			
>=25 - <30	1	(0.8)	2	3.45	0			
>=30 - <35	0				0			
>=35	0				0			
Malaise								
<25	2	(1.9)	2	3.94	1	(0.7)	38	56.34
>=25 - <30	0				1	(1.0)	4	8.04
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	2	10.03
>=35	0				0			
Medical device site bruise								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site dermatitis								
<25	3	(2.9)	3	5.91	3	(2.2)	4	5.93
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site erythema								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				2	(2.0)	3	6.03
>=30 - <35	0				0			
>=35	0				0			
Medical device site haematoma								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	14.26
Medical device site irritation								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site pain								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Medical device site pruritus								
<25	0				2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Medical device site rash								
<25	2	(1.9)	2	3.94	4	(3.0)	4	5.93
>=25 - <30	2	(1.7)	2	3.45	3	(2.9)	3	6.03
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	1	(4.8)	1	9.66	0			
Medical device site reaction								
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Oedema peripheral								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Pain								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	0				0			
Pyrexia								
<25	2	(1.9)	2	3.94	2	(1.5)	2	2.97
>=25 - <30	6	(5.1)	7	12.06	3	(2.9)	3	6.03
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			
Swelling face								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site pain								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<25	3	(2.9)	3	5.91	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	3	5.17	2	(2.0)	2	4.02
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Gallbladder disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Gallbladder polyp								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Hepatic calcification								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic steatosis								
<25	2	(1.9)	2	3.94	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Hypertransaminasaemia								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hypersensitivity								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Seasonal allergy								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Infections and infestations								
All								
<25	27	(25.7)	39	76.82	42	(31.1)	61	90.43
>=25 - <30	49	(41.5)	66	113.72	39	(38.2)	57	114.64
>=30 - <35	23	(50.0)	32	138.29	16	(39.0)	26	130.45
>=35	5	(23.8)	10	96.55	4	(28.6)	4	57.03
Abscess limb								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				1	(2.4)	2	10.03
>=35	0				0			
Acute sinusitis								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Breast abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Bronchitis								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctivitis								
<25	3	(2.9)	3	5.91	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Coronavirus infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
COVID-19								
<25	6	(5.7)	7	13.79	16	(11.9)	18	26.69
>=25 - <30	14	(11.9)	14	24.12	11	(10.8)	11	22.12
>=30 - <35	7	(15.2)	7	30.25	4	(9.8)	4	20.07
>=35	2	(9.5)	2	19.31	1	(7.1)	1	14.26
COVID-19 pneumonia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Cystitis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Cystitis escherichia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Eye infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Fungal skin infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Gastric infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis								
<25	2	(1.9)	3	5.91	2	(1.5)	2	2.97
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	1	(4.8)	1	9.66	0			
Gastroenteritis viral								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Gastrointestinal infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				2	(4.9)	3	15.05
>=35	0				0			
Genital infection fungal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	2	19.31	0			
Gingivitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Herpes zoster								
<25	0				2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hordeolum								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Infected cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Influenza								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	3	(2.9)	3	6.03
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Laryngitis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Localised infection								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lower respiratory tract infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Nasopharyngitis								
<25	11	(10.5)	13	25.61	13	(9.6)	16	23.72
>=25 - <30	14	(11.9)	16	27.57	17	(16.7)	21	42.23
>=30 - <35	8	(17.4)	12	51.86	5	(12.2)	5	25.09
>=35	1	(4.8)	1	9.66	1	(7.1)	1	14.26
Norovirus infection								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Otitis externa								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Otitis media								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Periodontitis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Pharyngitis								
<25	2	(1.9)	2	3.94	0			
>=25 - <30	3	(2.5)	3	5.17	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumonia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Respiratory tract infection								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Respiratory tract infection viral								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Rhinitis								
<25	0				2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	2	(2.0)	3	6.03
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Severe acute respiratory syndrome								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Sinusitis								
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	3	(6.5)	3	12.96	0			
>=35	0				0			
Skin infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Tinea cruris								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Tinea pedis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	1	(4.8)	1	9.66	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tonsillitis								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tooth abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	0				0			
Tooth infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Upper respiratory tract infection								
<25	3	(2.9)	3	5.91	1	(0.7)	1	1.48
>=25 - <30	3	(2.5)	3	5.17	2	(2.0)	3	6.03
>=30 - <35	0				3	(7.3)	3	15.05
>=35	0				1	(7.1)	1	14.26
Urinary tract infection								
<25	3	(2.9)	3	5.91	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	4	8.04
>=30 - <35	1	(2.2)	1	4.32	2	(4.9)	2	10.03
>=35	0				1	(7.1)	1	14.26
Vaginal infection								
<25	0				0			
>=25 - <30	1	(0.8)	2	3.45	0			
>=30 - <35	0				0			
>=35	0				0			
Viral infection								
<25	0				4	(3.0)	4	5.93
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvovaginitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injury, poisoning and procedural complications								
All								
<25	9	(8.6)	11	21.67	15	(11.1)	21	31.13
>=25 - <30	15	(12.7)	20	34.46	11	(10.8)	11	22.12
>=30 - <35	6	(13.0)	6	25.93	5	(12.2)	5	25.09
>=35	0				2	(14.3)	2	28.51
Accidental overdose								
<25	0				0			
>=25 - <30	5	(4.2)	6	10.34	0			
>=30 - <35	2	(4.3)	2	8.64	1	(2.4)	1	5.02
>=35	0				0			
Anaemia postoperative								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Animal scratch								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Arthropod bite								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Back injury								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Burns first degree								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	14.26
Clavicle fracture								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Contusion								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Corneal abrasion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	14.26
Epicondylitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Face injury								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fall								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Fibula fracture								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Hand fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Heat stroke								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Incorrect dose administered								
<25	0				0			
>=25 - <30	3	(2.5)	3	5.17	0			
>=30 - <35	0				0			
>=35	0				0			
Joint injury								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ligament sprain								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	3	(2.9)	3	5.91	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Limb injury								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Medication error								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Muscle strain								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Nerve injury								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Prescribed overdose								
<25	2	(1.9)	2	3.94	0			
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Procedural pain								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Product administration error								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Product dispensing error								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Radius fracture								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Road traffic accident								
<25	1	(1.0)	2	3.94	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Skin abrasion								
<25	0				0			
>=25 - <30	1	(0.8)	2	3.45	0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Skin laceration								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Tooth fracture								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination complication								
<25	2	(1.9)	2	3.94	5	(3.7)	8	11.86
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			
Wound								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Wound dehiscence								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Wrong product administered								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Investigations								
All								
<25	2	(1.9)	2	3.94	4	(3.0)	5	7.41

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	5	(4.2)	6	10.34	8	(7.8)	8	16.09
>=30 - <35	6	(13.0)	6	25.93	1	(2.4)	2	10.03
>=35	1	(4.8)	1	9.66	0			
Angiogram								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Aspartate aminotransferase increased								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Blood cholesterol increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Blood glucose increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Blood pressure increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	0				0			
Blood testosterone decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Blood triglycerides increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Blood uric acid increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Cardiac murmur								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Electrocardiogram abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Eosinophil count increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	2	10.03
>=35	0				0			
Haemoglobin decreased								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Heart rate increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic enzyme increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Hepatitis B virus test positive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Lipids abnormal								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Low density lipoprotein increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Mycobacterium tuberculosis complex test positive								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Occult blood positive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
SARS-CoV-2 test positive								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				3	(2.9)	3	6.03
>=30 - <35	0				0			
>=35	0				0			
Weight decreased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Weight increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
White blood cell count decreased								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Metabolism and nutrition disorders								
All								
<25	2	(1.9)	2	3.94	6	(4.4)	8	11.86
>=25 - <30	4	(3.4)	6	10.34	2	(2.0)	2	4.02
>=30 - <35	0				1	(2.4)	1	5.02
>=35	2	(9.5)	2	19.31	0			
Dehydration								
<25	0				1	(0.7)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypercholesterolaemia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hyperuricaemia								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemia								
<25	1	(1.0)	1	1.97	3	(2.2)	4	5.93
>=25 - <30	3	(2.5)	5	8.61	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Hyponatraemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Insulin resistance								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Obesity								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Vitamin D deficiency								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Musculoskeletal and connective tissue disorders								
All								
<25	9	(8.6)	10	19.70	16	(11.9)	37	54.85
>=25 - <30	13	(11.0)	14	24.12	14	(13.7)	17	34.19
>=30 - <35	4	(8.7)	6	25.93	6	(14.6)	6	30.10
>=35	1	(4.8)	1	9.66	3	(21.4)	3	42.77
Arthralgia								
<25	1	(1.0)	1	1.97	4	(3.0)	4	5.93
>=25 - <30	4	(3.4)	4	6.89	4	(3.9)	4	8.04
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				1	(7.1)	1	14.26
Arthritis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Back pain								
<25	0				5	(3.7)	19	28.17
>=25 - <30	3	(2.5)	3	5.17	3	(2.9)	3	6.03

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				2	(14.3)	2	28.51
Bursitis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Chondromalacia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Groin pain								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Limb discomfort								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Limb mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Muscle spasms								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Muscular weakness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Musculoskeletal stiffness								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Myalgia								
<25	2	(1.9)	2	3.94	4	(3.0)	4	5.93
>=25 - <30	0				2	(2.0)	3	6.03
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nodal osteoarthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Osteoarthritis								
<25	1	(1.0)	1	1.97	2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Pain in extremity								
<25	2	(1.9)	2	3.94	2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	4	(3.9)	4	8.04
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	1	(4.8)	1	9.66	0			
Periarthritis								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Rheumatoid arthritis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Synovial cyst								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tendonitis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tenosynovitis								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Trigger finger								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	1	(1.0)	1	1.97	1	(0.7)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	2	(4.3)	2	8.64	1	(2.4)	1	5.02
>=35	0				0			
Benign neoplasm of thyroid gland								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Benign renal neoplasm								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Eye naevus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Haemangioma of liver								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Melanocytic naevus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Uterine leiomyoma								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Nervous system disorders								
All								
<25	14	(13.3)	26	51.21	11	(8.1)	63	93.40

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	7	(5.9)	10	17.23	8	(7.8)	10	20.11
>=30 - <35	4	(8.7)	8	34.57	3	(7.3)	3	15.05
>=35	2	(9.5)	2	19.31	2	(14.3)	2	28.51
Autonomic nervous system imbalance								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Burning sensation								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Carpal tunnel syndrome								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cervicobrachial syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Diabetic neuropathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Disturbance in attention								
<25	1	(1.0)	9	17.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dizziness								
<25	2	(1.9)	3	5.91	2	(1.5)	3	4.45
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dizziness postural								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Encephalopathy								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Haemorrhage intracranial								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Headache								
<25	6	(5.7)	8	15.76	3	(2.2)	4	5.93
>=25 - <30	4	(3.4)	5	8.61	5	(4.9)	7	14.08
>=30 - <35	3	(6.5)	6	25.93	1	(2.4)	1	5.02
>=35	0				1	(7.1)	1	14.26
Hypoaesthesia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Hypoglycaemic seizure								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypoglycaemic unconsciousness								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypotonia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Loss of consciousness								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Migraine								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	2	3.45	1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Neuropathy peripheral								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post herpetic neuralgia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sinus headache								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	14.26
Somnolence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Speech disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Syncope								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Tremor								
<25	1	(1.0)	1	1.97	1	(0.7)	48	71.16
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<25	0				4	(3.0)	5	7.41
>=25 - <30	3	(2.5)	3	5.17	2	(2.0)	2	4.02
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	1	(4.8)	1	9.66	0			
Anxiety								
<25	0				2	(1.5)	2	2.97
>=25 - <30	1	(0.8)	1	1.72	2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Attention deficit hyperactivity disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Depressed mood								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Depression								
<25	0				3	(2.2)	3	4.45
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Insomnia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Sleep disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<25	2	(1.9)	2	3.94	0			
>=25 - <30	1	(0.8)	1	1.72	2	(2.0)	5	10.06
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Chronic kidney disease								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Diabetic nephropathy								
<25	0				0			
>=25 - <30	0				2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Hydrocalyx								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Hypertensive nephropathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Microalbuminuria								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Renal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Renal pain								
<25	2	(1.9)	2	3.94	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Reproductive system and breast disorders								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	2	(1.9)	2	3.94	1	(0.7)	3	4.45
>=25 - <30	1	(0.8)	1	1.72	2	(2.0)	2	4.02
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	0				0			
Benign prostatic hyperplasia								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Dysmenorrhoea								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Ectropion of cervix								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fibrocystic breast disease								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian disorder								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Penile pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	5.02
>=35	0				0			
Premenstrual syndrome								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Prostatomegaly								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
All								
<25	8	(7.6)	9	17.73	12	(8.9)	15	22.24
>=25 - <30	9	(7.6)	13	22.40	6	(5.9)	9	18.10
>=30 - <35	4	(8.7)	4	17.29	3	(7.3)	5	25.09
>=35	0				0			
Allergic cough								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Bronchial hyperreactivity								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cough								
<25	1	(1.0)	1	1.97	3	(2.2)	3	4.45
>=25 - <30	2	(1.7)	4	6.89	2	(2.0)	3	6.03
>=30 - <35	0				3	(7.3)	3	15.05
>=35	0				0			
Dyspnoea exertional								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Epistaxis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hiccups								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nasal congestion								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Oropharyngeal pain								
<25	3	(2.9)	3	5.91	1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	2	8.64	2	(4.9)	2	10.03
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pleurisy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Productive cough								
<25	0				2	(1.5)	2	2.97
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pulmonary congestion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Respiratory disorder								
<25	2	(1.9)	2	3.94	2	(1.5)	2	2.97
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	0				0			
>=35	0				0			
Rhinitis allergic								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Rhinorrhoea								
<25	0				4	(3.0)	4	5.93
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Sinus congestion								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Sneezing								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Throat irritation								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Upper-airway cough syndrome								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Skin and subcutaneous tissue disorders								
All								
<25	4	(3.8)	4	7.88	16	(11.9)	20	29.65
>=25 - <30	11	(9.3)	11	18.95	8	(7.8)	12	24.13
>=30 - <35	5	(10.9)	5	21.61	0			
>=35	4	(19.0)	4	38.62	0			
Alopecia								
<25	0				0			
>=25 - <30	2	(1.7)	2	3.45	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Angioedema								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Blister								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Chronic spontaneous urticaria								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cold sweat								
<25	0				3	(2.2)	5	7.41
>=25 - <30	0				2	(2.0)	4	8.04
>=30 - <35	0				0			
>=35	0				0			
Dermal cyst								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Dermatitis								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	3	(2.5)	3	5.17	1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis atopic								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Dermatitis contact								
<25	0				4	(3.0)	4	5.93
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Dry skin								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Eczema								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			
Erythema								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hidradenitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Hyperkeratosis								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ingrown hair								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lichen sclerosus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Macule								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	4.32	0			
>=35	0				0			
Pruritus								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Rash								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	2	8.64	0			
>=35	1	(4.8)	1	9.66	0			
Rash erythematous								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Skin irritation								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	9.66	0			
Skin lesion								
<25	0				1	(0.7)	1	1.48
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Telangiectasia								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria								
<25	0				1	(0.7)	1	1.48
>=25 - <30	0				2	(2.0)	2	4.02
>=30 - <35	0				0			
>=35	0				0			
Xeroderma								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac ablation								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Skin neoplasm excision								
<25	0				0			
>=25 - <30	1	(0.8)	1	1.72	0			
>=30 - <35	0				0			
>=35	0				0			
Vascular disorders								
All								
<25	1	(1.0)	1	1.97	1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	2	(2.0)	2	4.02
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	2	(9.5)	2	19.31	0			
Arteriosclerosis								
<25	1	(1.0)	1	1.97	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypertension								
<25	0				1	(0.7)	1	1.48
>=25 - <30	2	(1.7)	2	3.45	1	(1.0)	1	2.01
>=30 - <35	1	(2.2)	1	4.32	1	(2.4)	1	5.02
>=35	2	(9.5)	2	19.31	0			
Varicose vein								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	2.01
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.41 Adverse events by baseline renal function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	224				222			
Mild impairment	223				213			
Moderate or severe impairment	45				57			
PYE (years)								
Normal	221.46				220.19			
Mild impairment	220.61				210.98			
Moderate or severe impairment	43.81				53.87			
Events								
Normal	156	(69.6)	534	241.13	146	(65.8)	446	202.55
Mild impairment	165	(74.0)	582	263.81	151	(70.9)	536	254.05
Moderate or severe impairment	30	(66.7)	111	253.38	38	(66.7)	180	334.16
Serious								
Yes								
Normal	19	(8.5)	28	12.64	14	(6.3)	17	7.72
Mild impairment	24	(10.8)	32	14.51	26	(12.2)	37	17.54
Moderate or severe impairment	8	(17.8)	14	31.96	9	(15.8)	19	35.27
No								
Normal	152	(67.9)	506	228.48	146	(65.8)	429	194.83
Mild impairment	158	(70.9)	550	249.31	145	(68.1)	499	236.52
Moderate or severe impairment	28	(62.2)	97	221.42	37	(64.9)	161	298.88
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	8	(3.6)	10	4.52	4	(1.8)	5	2.27
Mild impairment	4	(1.8)	8	3.63	11	(5.2)	15	7.11
Moderate or severe impairment	6	(13.3)	8	18.26	5	(8.8)	14	25.99
Moderate								
Normal	70	(31.3)	132	59.60	69	(31.1)	116	52.68
Mild impairment	66	(29.6)	117	53.03	53	(24.9)	107	50.72
Moderate or severe impairment	16	(35.6)	31	70.76	14	(24.6)	28	51.98
Mild								
Normal	128	(57.1)	392	177.01	120	(54.1)	325	147.60
Mild impairment	142	(63.7)	457	207.15	131	(61.5)	414	196.23
Moderate or severe impairment	22	(48.9)	72	164.35	35	(61.4)	138	256.19
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Related to basal insulin								
Probable								
Normal	5	(2.2)	6	2.71	13	(5.9)	17	7.72
Mild impairment	11	(4.9)	17	7.71	14	(6.6)	22	10.43
Moderate or severe impairment	3	(6.7)	4	9.13	2	(3.5)	6	11.14
Possible								
Normal	9	(4.0)	12	5.42	10	(4.5)	13	5.90
Mild impairment	22	(9.9)	29	13.15	15	(7.0)	24	11.38
Moderate or severe impairment	3	(6.7)	5	11.41	6	(10.5)	9	16.71
Unlikely								
Normal	152	(67.9)	515	232.55	140	(63.1)	416	188.93
Mild impairment	161	(72.2)	536	242.96	149	(70.0)	489	231.78
Moderate or severe impairment	30	(66.7)	102	232.83	36	(63.2)	165	306.31
Missing								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
No								
Normal	155	(69.2)	533	240.68	146	(65.8)	446	202.55
Mild impairment	165	(74.0)	582	263.81	151	(70.9)	535	253.58
Moderate or severe impairment	30	(66.7)	111	253.38	38	(66.7)	180	334.16
NA								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	2	0.91	1	(0.5)	2	0.95
Moderate or severe impairment	2	(4.4)	2	4.57	1	(1.8)	1	1.86
Not recovered/not resolved								
Normal	63	(28.1)	127	57.35	57	(25.7)	102	46.32
Mild impairment	79	(35.4)	165	74.79	80	(37.6)	144	68.25
Moderate or severe impairment	15	(33.3)	32	73.05	22	(38.6)	44	81.68
Recovered/resolved with sequelae								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	3	(1.3)	3	1.36	3	(1.4)	4	1.90
Moderate or severe impairment	2	(4.4)	2	4.57	0			
Recovering/resolving								
Normal	6	(2.7)	10	4.52	9	(4.1)	9	4.09
Mild impairment	10	(4.5)	13	5.89	8	(3.8)	9	4.27
Moderate or severe impairment	3	(6.7)	3	6.85	3	(5.3)	3	5.57
Recovered/resolved								
Normal	135	(60.3)	395	178.36	129	(58.1)	333	151.23
Mild impairment	147	(65.9)	399	180.86	131	(61.5)	377	178.69
Moderate or severe impairment	26	(57.8)	72	164.35	33	(57.9)	132	245.05
Unknown								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.42 Adverse events by baseline renal function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	94				109			
Mild impairment	134				108			
Moderate impairment	34				46			
PYE (years)								
Normal	55.36				62.74			
Mild impairment	80.04				63.33			
Moderate impairment	19.84				26.70			
Events								
Normal	58	(61.7)	165	298.05	52	(47.7)	129	205.63
Mild impairment	80	(59.7)	248	309.83	59	(54.6)	133	210.00
Moderate impairment	23	(67.6)	53	267.08	23	(50.0)	66	247.14
Serious								
Yes								
Normal	6	(6.4)	11	19.87	4	(3.7)	7	11.16
Mild impairment	11	(8.2)	12	14.99	7	(6.5)	7	11.05
Moderate impairment	5	(14.7)	7	35.28	5	(10.9)	6	22.47
No								
Normal	57	(60.6)	154	278.18	51	(46.8)	122	194.47
Mild impairment	78	(58.2)	236	294.84	57	(52.8)	126	198.95
Moderate impairment	23	(67.6)	46	231.81	20	(43.5)	60	224.68
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	5	(5.3)	8	14.45	6	(5.5)	7	11.16
Mild impairment	3	(2.2)	3	3.75	2	(1.9)	2	3.16
Moderate impairment	3	(8.8)	6	30.24	3	(6.5)	4	14.98
Moderate								
Normal	28	(29.8)	54	97.54	27	(24.8)	44	70.14
Mild impairment	28	(20.9)	55	68.71	21	(19.4)	31	48.95
Moderate impairment	8	(23.5)	13	65.51	6	(13.0)	7	26.21
Mild								
Normal	48	(51.1)	103	186.06	41	(37.6)	78	124.33
Mild impairment	67	(50.0)	190	237.37	48	(44.4)	100	157.90
Moderate impairment	17	(50.0)	34	171.34	20	(43.5)	55	205.95
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Related to basal insulin								
Probable								
Normal	4	(4.3)	4	7.23	2	(1.8)	4	6.38
Mild impairment	5	(3.7)	5	6.25	3	(2.8)	8	12.63
Moderate impairment	0				1	(2.2)	1	3.74
Possible								
Normal	6	(6.4)	8	14.45	4	(3.7)	4	6.38
Mild impairment	10	(7.5)	18	22.49	2	(1.9)	2	3.16
Moderate impairment	0				1	(2.2)	1	3.74
Unlikely								
Normal	55	(58.5)	149	269.15	50	(45.9)	120	191.28
Mild impairment	78	(58.2)	220	274.85	58	(53.7)	122	192.64
Moderate impairment	22	(64.7)	52	262.04	22	(47.8)	63	235.91
Missing								
Normal	2	(2.1)	4	7.23	1	(0.9)	1	1.59
Mild impairment	3	(2.2)	5	6.25	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	1	(2.2)	1	3.74

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
No								
Normal	58	(61.7)	161	290.83	50	(45.9)	127	202.44
Mild impairment	80	(59.7)	242	302.33	59	(54.6)	132	208.43
Moderate impairment	22	(64.7)	51	257.01	22	(47.8)	64	239.66
NA								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Missing								
Normal	2	(2.1)	4	7.23	1	(0.9)	1	1.59
Mild impairment	3	(2.2)	5	6.25	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	1	(2.2)	1	3.74

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	2	(5.9)	3	15.12	1	(2.2)	1	3.74
Not recovered/not resolved								
Normal	20	(21.3)	41	74.06	17	(15.6)	24	38.26
Mild impairment	27	(20.1)	43	53.72	21	(19.4)	27	42.63
Moderate impairment	8	(23.5)	13	65.51	10	(21.7)	12	44.94
Recovered/resolved with sequelae								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Recovering/resolving								
Normal	7	(7.4)	9	16.26	4	(3.7)	5	7.97
Mild impairment	12	(9.0)	15	18.74	5	(4.6)	5	7.89
Moderate impairment	0				7	(15.2)	7	26.21
Recovered/resolved								
Normal	46	(48.9)	115	207.73	41	(37.6)	100	159.40
Mild impairment	67	(50.0)	190	237.37	43	(39.8)	100	157.90
Moderate impairment	22	(64.7)	37	186.45	16	(34.8)	45	168.51
Unknown								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.43 Adverse events by baseline renal function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	123				127			
Mild impairment	121				120			
Moderate impairment	47				44			
PYE (years)								
Normal	70.74				72.58			
Mild impairment	69.79				70.23			
Moderate impairment	26.83				23.99			
Events								
Normal	64	(52.0)	186	262.92	57	(44.9)	223	307.26
Mild impairment	75	(62.0)	197	282.28	81	(67.5)	232	330.34
Moderate impairment	32	(68.1)	72	268.35	29	(65.9)	95	396.01
Serious								
Yes								
Normal	6	(4.9)	17	24.03	10	(7.9)	17	23.42
Mild impairment	12	(9.9)	14	20.06	8	(6.7)	8	11.39
Moderate impairment	4	(8.5)	4	14.91	7	(15.9)	8	33.35
No								
Normal	63	(51.2)	169	238.89	56	(44.1)	206	283.83
Mild impairment	70	(57.9)	183	262.22	78	(65.0)	224	318.95
Moderate impairment	31	(66.0)	68	253.44	26	(59.1)	87	362.67
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	5	(4.1)	12	16.96	2	(1.6)	2	2.76
Mild impairment	6	(5.0)	6	8.60	4	(3.3)	4	5.70
Moderate impairment	2	(4.3)	2	7.45	6	(13.6)	8	33.35
Moderate								
Normal	24	(19.5)	48	67.85	26	(20.5)	65	89.56
Mild impairment	26	(21.5)	36	51.58	25	(20.8)	38	54.11
Moderate impairment	9	(19.1)	15	55.91	10	(22.7)	18	75.03
Mild								
Normal	51	(41.5)	126	178.11	53	(41.7)	156	214.94
Mild impairment	61	(50.4)	155	222.10	71	(59.2)	190	270.53
Moderate impairment	26	(55.3)	55	204.99	24	(54.5)	69	287.63
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Related to basal insulin								
Probable								
Normal	3	(2.4)	6	8.48	2	(1.6)	2	2.76
Mild impairment	5	(4.1)	6	8.60	4	(3.3)	5	7.12
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Possible								
Normal	6	(4.9)	6	8.48	7	(5.5)	10	13.78
Mild impairment	13	(10.7)	19	27.23	7	(5.8)	18	25.63
Moderate impairment	4	(8.5)	9	33.54	3	(6.8)	15	62.53
Unlikely								
Normal	60	(48.8)	174	245.96	55	(43.3)	211	290.72
Mild impairment	67	(55.4)	172	246.46	78	(65.0)	209	297.59
Moderate impairment	30	(63.8)	62	231.08	29	(65.9)	79	329.32
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	3	(2.4)	3	4.24	1	(0.8)	2	2.76
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				2	(4.5)	2	8.34
No								
Normal	63	(51.2)	183	258.68	57	(44.9)	220	303.12
Mild impairment	75	(62.0)	195	279.42	81	(67.5)	232	330.34
Moderate impairment	32	(68.1)	72	268.35	29	(65.9)	93	387.68
NA								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	1	(0.8)	3	4.24	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Not recovered/not resolved								
Normal	31	(25.2)	52	73.51	26	(20.5)	66	90.94
Mild impairment	37	(30.6)	71	101.74	36	(30.0)	66	93.98
Moderate impairment	10	(21.3)	16	59.63	11	(25.0)	20	83.37
Recovered/resolved with sequelae								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				2	(4.5)	2	8.34
Recovering/resolving								
Normal	8	(6.5)	24	33.93	5	(3.9)	8	11.02
Mild impairment	4	(3.3)	4	5.73	8	(6.7)	10	14.24
Moderate impairment	4	(8.5)	4	14.91	3	(6.8)	4	16.67
Recovered/resolved								
Normal	54	(43.9)	107	151.25	54	(42.5)	148	203.92
Mild impairment	61	(50.4)	121	173.38	63	(52.5)	156	222.12
Moderate impairment	28	(59.6)	52	193.81	25	(56.8)	69	287.63
Unknown								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.44 Adverse events by baseline renal function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	197				190			
Mild impairment	88				93			
Moderate impairment	5				9			
PYE (years)								
Normal	97.36				93.48			
Mild impairment	42.42				46.13			
Moderate impairment	2.54				4.51			
Events								
Normal	124	(62.9)	319	327.67	118	(62.1)	325	347.65
Mild impairment	62	(70.5)	182	429.07	65	(69.9)	281	609.18
Moderate impairment	3	(60.0)	6	236.66	7	(77.8)	13	288.30
Serious								
Yes								
Normal	6	(3.0)	8	8.22	5	(2.6)	7	7.49
Mild impairment	5	(5.7)	7	16.50	2	(2.2)	2	4.34
Moderate impairment	0				0			
No								
Normal	121	(61.4)	311	319.45	116	(61.1)	318	340.17
Mild impairment	61	(69.3)	175	412.57	64	(68.8)	279	604.85
Moderate impairment	3	(60.0)	6	236.66	7	(77.8)	13	288.30
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	6	(3.0)	6	6.16	3	(1.6)	4	4.28
Mild impairment	3	(3.4)	4	9.43	1	(1.1)	1	2.17
Moderate impairment	0				0			
Moderate								
Normal	33	(16.8)	59	60.60	35	(18.4)	62	66.32
Mild impairment	18	(20.5)	31	73.08	13	(14.0)	23	49.86
Moderate impairment	0				3	(33.3)	4	88.71
Mild								
Normal	109	(55.3)	254	260.90	107	(56.3)	259	277.05
Mild impairment	57	(64.8)	147	346.55	57	(61.3)	257	557.15
Moderate impairment	3	(60.0)	6	236.66	6	(66.7)	9	199.59
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Related to basal insulin								
Probable								
Normal	11	(5.6)	11	11.30	5	(2.6)	5	5.35
Mild impairment	6	(6.8)	9	21.22	2	(2.2)	3	6.50
Moderate impairment	0				0			
Possible								
Normal	11	(5.6)	13	13.35	7	(3.7)	8	8.56
Mild impairment	11	(12.5)	13	30.65	9	(9.7)	32	69.37
Moderate impairment	0				1	(11.1)	1	22.18
Unlikely								
Normal	117	(59.4)	295	303.01	118	(62.1)	312	333.75
Mild impairment	58	(65.9)	160	377.20	65	(69.9)	246	533.31
Moderate impairment	3	(60.0)	6	236.66	6	(66.7)	12	266.12
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
No								
Normal	124	(62.9)	319	327.67	118	(62.1)	325	347.65
Mild impairment	62	(70.5)	182	429.07	65	(69.9)	281	609.18
Moderate impairment	3	(60.0)	6	236.66	7	(77.8)	13	288.30
NA								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt ; variable(s): OTMTDURY GFRGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & ANELFL == "Y" & ANL06FL == "Y"
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Adverse events by baseline renal function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Not recovered/not resolved								
Normal	49	(24.9)	64	65.74	43	(22.6)	75	80.23
Mild impairment	37	(42.0)	70	165.03	38	(40.9)	67	145.25
Moderate impairment	0				2	(22.2)	2	44.35
Recovered/resolved with sequelae								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Recovering/resolving								
Normal	6	(3.0)	6	6.16	2	(1.1)	2	2.14
Mild impairment	0				3	(3.2)	6	13.01
Moderate impairment	0				0			
Recovered/resolved								
Normal	108	(54.8)	249	255.76	104	(54.7)	247	264.22
Mild impairment	49	(55.7)	111	261.68	50	(53.8)	206	446.59
Moderate impairment	3	(60.0)	6	236.66	7	(77.8)	11	243.94
Unknown								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.45 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	224				222			
Mild impairment	223				213			
Moderate or severe impairment	45				57			
PYE (years)								
Normal	221.46				220.19			
Mild impairment	220.61				210.98			
Moderate or severe impairment	43.81				53.87			
Events								
Normal	156	(69.6)	534	241.13	146	(65.8)	446	202.55
Mild impairment	165	(74.0)	582	263.81	151	(70.9)	536	254.05
Moderate or severe impairment	30	(66.7)	111	253.38	38	(66.7)	180	334.16

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	3	(1.3)	3	1.35	6	(2.7)	6	2.72
Mild impairment	6	(2.7)	6	2.72	4	(1.9)	4	1.90
Moderate or severe impairment	2	(4.4)	2	4.57	1	(1.8)	1	1.86
Anaemia								
Normal	1	(0.4)	1	0.45	3	(1.4)	3	1.36
Mild impairment	3	(1.3)	3	1.36	3	(1.4)	3	1.42
Moderate or severe impairment	2	(4.4)	2	4.57	0			
Blood loss anaemia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Eosinophilia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hypochromic anaemia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Iron deficiency anaemia								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lymphadenopathy								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Polycythaemia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Thrombocytopenia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	11	(4.9)	18	8.13	8	(3.6)	10	4.54
Mild impairment	18	(8.1)	32	14.51	14	(6.6)	17	8.06
Moderate or severe impairment	8	(17.8)	13	29.67	8	(14.0)	11	20.42
Acute coronary syndrome								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Acute myocardial infarction								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	2	0.95
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Angina pectoris								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Angina unstable								
Normal	3	(1.3)	3	1.35	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve calcification								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve incompetence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Arrhythmia								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Atrial fibrillation								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	5	(2.2)	5	2.27	2	(0.9)	2	0.95
Moderate or severe impairment	2	(4.4)	3	6.85	2	(3.5)	2	3.71
Atrial flutter								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrial thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Atrioventricular block complete								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Bradycardia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Bundle branch block right								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	3	1.42
Moderate or severe impairment	0				0			
Cardiac dysfunction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Cardiac failure								
Normal	0				0			
Mild impairment	3	(1.3)	3	1.36	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Cardiac failure chronic								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac failure congestive								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Cardiac ventricular thrombosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Chronic coronary syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronary artery disease								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Coronary artery occlusion								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Diastolic dysfunction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Left atrial dilatation								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Left ventricular dysfunction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Left ventricular hypertrophy								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Mitral valve incompetence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Myocardial infarction								
Normal	3	(1.3)	3	1.35	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Myocardial ischaemia								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Palpitations								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pericardial effusion								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Pericarditis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Sinus arrhythmia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Sinus bradycardia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinus tachycardia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Supraventricular extrasystoles								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Tachycardia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Tricuspid valve incompetence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Ventricular extrasystoles								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hydrocele								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Type V hyperlipidaemia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	5	(2.2)	5	2.26	1	(0.5)	1	0.45
Mild impairment	3	(1.3)	3	1.36	6	(2.8)	6	2.84
Moderate or severe impairment	0				2	(3.5)	3	5.57
Ear inflammation								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear pain								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eustachian tube dysfunction								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypoacusis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Presbyacusis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Tinnitus								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Vertigo								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	3	(1.3)	3	1.36	4	(1.9)	4	1.90
Moderate or severe impairment	0				1	(1.8)	2	3.71
Vertigo positional								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	0				3	(1.4)	3	1.36
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	3	1.42
Moderate or severe impairment	0				0			
Goitre								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperplasia adrenal								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperprolactinaemia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperthyroidism								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypothyroidism								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Thyroid mass								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Eye disorders								
All								
Normal	4	(1.8)	4	1.81	5	(2.3)	7	3.18
Mild impairment	18	(8.1)	28	12.69	15	(7.0)	18	8.53
Moderate or severe impairment	3	(6.7)	3	6.85	5	(8.8)	7	12.99
Acquired epiblepharon								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Asthenopia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Astigmatism								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Blepharitis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Cataract								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	7	(3.1)	9	4.08	3	(1.4)	4	1.90
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Conjunctival erosion								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival haemorrhage								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctivitis allergic								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	0			
Moderate or severe impairment	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic retinal oedema								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Diabetic retinopathy								
Normal	0				0			
Mild impairment	3	(1.3)	3	1.36	2	(0.9)	2	0.95
Moderate or severe impairment	0				2	(3.5)	2	3.71

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diplopia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Dry eye								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	5	(2.3)	5	2.37
Moderate or severe impairment	0				0			
Eye discharge								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Eye inflammation								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Eye pain								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Glaucoma								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Macular oedema								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Normal tension glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Ocular hypertension								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Optic disc vascular disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Photophobia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Post thrombotic retinopathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Retinal aneurysm								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal artery occlusion								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Retinal detachment								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal tear								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Retinal vein occlusion								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Scintillating scotoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Uveitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Visual impairment								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vitreous detachment								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Gastrointestinal disorders								
All								
Normal	38	(17.0)	61	27.54	27	(12.2)	34	15.44
Mild impairment	37	(16.6)	61	27.65	33	(15.5)	54	25.59
Moderate or severe impairment	8	(17.8)	14	31.96	14	(24.6)	26	48.27
Abdominal discomfort								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Abdominal distension								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Abdominal pain								
Normal	4	(1.8)	4	1.81	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	3	(1.4)	3	1.42
Moderate or severe impairment	0				1	(1.8)	1	1.86
Abdominal pain lower								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Abdominal pain upper								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	4	1.90

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Acid peptic disease								
Normal	0				2	(0.9)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal fissure								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Anal pruritus								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Chronic gastritis								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				2	(3.5)	2	3.71
Colitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				2	(3.5)	2	3.71
Colitis ischaemic								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Colitis microscopic								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Constipation								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Crohn's disease								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dental caries								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	3	(1.3)	4	1.81	1	(0.5)	1	0.47
Moderate or severe impairment	2	(4.4)	2	4.57	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diarrhoea								
Normal	11	(4.9)	16	7.22	9	(4.1)	9	4.09
Mild impairment	13	(5.8)	18	8.16	7	(3.3)	7	3.32
Moderate or severe impairment	7	(15.6)	9	20.54	5	(8.8)	6	11.14
Diverticulum								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Diverticulum intestinal								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dry mouth								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Duodenitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Dyspepsia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Enteritis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Enterocolitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	3	1.36	0			
Moderate or severe impairment	0				0			
Epigastric discomfort								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Flatulence								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Food poisoning								
Normal	1	(0.4)	1	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Frequent bowel movements								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Gastric disorder								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric polyps								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Gastrointestinal inflammation								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Gastrooesophageal reflux disease								
Normal	4	(1.8)	4	1.81	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				3	(5.3)	3	5.57
Haematochezia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Haemorrhoids								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Hiatus hernia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperaesthesia teeth								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperchlorhydria								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ileus								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inguinal hernia								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Intra-abdominal haematoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Large intestine polyp								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				2	(0.9)	3	1.42
Moderate or severe impairment	0				0			
Loose tooth								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Melaena								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nausea								
Normal	6	(2.7)	7	3.16	1	(0.5)	1	0.45
Mild impairment	6	(2.7)	6	2.72	2	(0.9)	3	1.42
Moderate or severe impairment	3	(6.7)	3	6.85	2	(3.5)	3	5.57
Oral discomfort								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Pancreatitis acute								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Pancreatitis chronic								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Periodontal disease								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Periodontal inflammation								
Normal	0				1	(0.5)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rectal polyp								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Rectal prolapse								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Stomatitis								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Tooth disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Tooth impacted								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Toothache								
Normal	6	(2.7)	6	2.71	0			
Mild impairment	3	(1.3)	3	1.36	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Ulcerative gastritis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Umbilical hernia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Vomiting								
Normal	2	(0.9)	2	0.90	3	(1.4)	3	1.36
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	4	1.90
Moderate or severe impairment	0				2	(3.5)	4	7.43
General disorders and administration site conditions								
All								
Normal	29	(12.9)	37	16.71	31	(14.0)	44	19.98
Mild impairment	39	(17.5)	68	30.82	36	(16.9)	52	24.65
Moderate or severe impairment	7	(15.6)	9	20.54	11	(19.3)	14	25.99
Asthenia								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	3	(1.3)	3	1.36	3	(1.4)	3	1.42
Moderate or severe impairment	0				0			
Chest discomfort								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Chest pain								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Chills								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Death								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Discomfort								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Drug intolerance								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Early satiety								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Fatigue								
Normal	4	(1.8)	4	1.81	3	(1.4)	3	1.36
Mild impairment	8	(3.6)	9	4.08	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Feeling abnormal								
Normal	0				0			
Mild impairment	1	(0.4)	3	1.36	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Feeling hot								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gait disturbance								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hunger								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Implant site pruritus								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Inflammation								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Influenza like illness								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site bruising								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Injection site dermatitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site erythema								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Injection site haemorrhage								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Injection site hypersensitivity								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Injection site hypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Injection site mass								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site pain								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Injection site reaction								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site urticaria								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Malaise								
Normal	0				1	(0.5)	2	0.91
Mild impairment	5	(2.2)	6	2.72	6	(2.8)	7	3.32
Moderate or severe impairment	0				1	(1.8)	1	1.86

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site bruise								
Normal	2	(0.9)	3	1.35	1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Medical device site dermatitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	5	2.27	5	(2.3)	11	5.21
Moderate or severe impairment	0				2	(3.5)	2	3.71
Medical device site eczema								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Medical device site erythema								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site haematoma								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site haemorrhage								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	2	(4.4)	2	4.57	1	(1.8)	1	1.86
Medical device site hypersensitivity								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site inflammation								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pain								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pruritus								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Medical device site reaction								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Non-cardiac chest pain								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oedema								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Oedema peripheral								
Normal	1	(0.4)	1	0.45	4	(1.8)	5	2.27
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	3	(6.7)	3	6.85	0			
Pain								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	3	1.42
Moderate or severe impairment	0				1	(1.8)	1	1.86
Peripheral swelling								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Procedural failure								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Pyrexia								
Normal	5	(2.2)	5	2.26	6	(2.7)	7	3.18
Mild impairment	11	(4.9)	12	5.44	13	(6.1)	13	6.16
Moderate or severe impairment	1	(2.2)	1	2.28	2	(3.5)	2	3.71
Swelling								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Thirst								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site erythema								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
Normal	0				3	(1.4)	3	1.36
Mild impairment	4	(1.8)	5	2.27	0			
Moderate or severe impairment	0				0			
Vaccination site reaction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hepatobiliary disorders								
All								
Normal	4	(1.8)	7	3.16	2	(0.9)	2	0.91
Mild impairment	5	(2.2)	5	2.27	3	(1.4)	4	1.90
Moderate or severe impairment	0				1	(1.8)	1	1.86
Cholelithiasis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic cirrhosis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic cyst								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hepatic function abnormal								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hepatic steatosis								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	3	(1.3)	3	1.36	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Hypertransaminasaemia								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Liver disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nonalcoholic fatty liver disease								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Steatohepatitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Immune system disorders								
All								
Normal	1	(0.4)	2	0.90	3	(1.4)	4	1.82
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Allergy to arthropod bite								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Immunisation reaction								
Normal	0				1	(0.5)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Seasonal allergy								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Infections and infestations								
All								
Normal	84	(37.5)	150	67.73	94	(42.3)	142	64.49
Mild impairment	73	(32.7)	96	43.52	81	(38.0)	117	55.46
Moderate or severe impairment	12	(26.7)	17	38.81	18	(31.6)	28	51.98

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Abscess								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Acarodermatitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Acute sinusitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal abscess								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Asymptomatic COVID-19								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Bacterial infection								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Balanitis candida								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body tinea								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Breast abscess								
Normal	0				2	(0.9)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast cellulitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Bronchitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	5	(2.2)	5	2.26	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Candida infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cellulitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Chlamydial infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic hepatitis C								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic sinusitis								
Normal	0				2	(0.9)	2	0.91
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Chronic tonsillitis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Clostridium difficile infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Conjunctivitis								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Coronavirus infection								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	3	1.42
Moderate or severe impairment	0				0			
COVID-19								
Normal	31	(13.8)	31	14.00	34	(15.3)	34	15.44
Mild impairment	15	(6.7)	15	6.80	25	(11.7)	26	12.32

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	3	(6.7)	3	6.85	2	(3.5)	2	3.71
COVID-19 pneumonia								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	3	(1.3)	3	1.36	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Cystitis								
Normal	0				3	(1.4)	4	1.82
Mild impairment	5	(2.2)	6	2.72	4	(1.9)	4	1.90
Moderate or severe impairment	0				1	(1.8)	1	1.86
Dermatophytosis of nail								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Diverticulitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Ear infection								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Empyema								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endophthalmitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epididymitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Erysipelas								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Escherichia urinary tract infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye infection bacterial								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Folliculitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Fungal balanitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fungal infection								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Furuncle								
Normal	1	(0.4)	2	0.90	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastroenteritis								
Normal	4	(1.8)	4	1.81	2	(0.9)	2	0.91
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Gastroenteritis norovirus								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastroenteritis viral								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Gastrointestinal infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Genital infection fungal								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Giardiasis								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Gingivitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Helicobacter gastritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Helicobacter infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Herpes dermatitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Herpes simplex								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Herpes virus infection								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Herpes zoster								
Normal	3	(1.3)	3	1.35	1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	4	(1.9)	4	1.90
Moderate or severe impairment	0				1	(1.8)	1	1.86
Hordeolum								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Infected bite								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Influenza								
Normal	0				2	(0.9)	2	0.91
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Labyrinthitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Laryngitis								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngopharyngitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Localised infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Lower respiratory tract infection								
Normal	3	(1.3)	3	1.35	1	(0.5)	3	1.36
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Lyme disease								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Mastitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nail infection								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasopharyngitis								
Normal	14	(6.3)	16	7.22	13	(5.9)	14	6.36
Mild impairment	15	(6.7)	19	8.61	17	(8.0)	18	8.53
Moderate or severe impairment	1	(2.2)	1	2.28	4	(7.0)	5	9.28
Onychomycosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Oophoritis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Oral herpes								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Oropharyngeal candidiasis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteomyelitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Otitis media								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Otitis media acute								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Otitis media chronic								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Parotitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Peri-implantitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Pericoronitis								
Normal	0				0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Periodontitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	2	(4.4)	2	4.57	0			
Pharyngitis								
Normal	8	(3.6)	10	4.52	7	(3.2)	8	3.63
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Pharyngotonsillitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Pneumonia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Post procedural infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Pulpitis dental								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Purulence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Respiratory syncytial virus infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Respiratory tract infection								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	3	(1.4)	3	1.42
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Respiratory tract infection viral								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis								
Normal	5	(2.2)	5	2.26	3	(1.4)	3	1.36
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Rotavirus infection								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Salpingitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Sepsis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinusitis								
Normal	3	(1.3)	4	1.81	5	(2.3)	7	3.18
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Skin bacterial infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Skin infection								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Subcutaneous abscess								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Tinea infection								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tonsillitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Tooth abscess								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	2	0.95
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Tooth infection								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tracheitis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Upper respiratory tract infection								
Normal	14	(6.3)	20	9.03	4	(1.8)	4	1.82
Mild impairment	7	(3.1)	7	3.17	6	(2.8)	7	3.32
Moderate or severe impairment	2	(4.4)	3	6.85	3	(5.3)	3	5.57
Urethritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract infection								
Normal	4	(1.8)	4	1.81	10	(4.5)	10	4.54
Mild impairment	2	(0.9)	2	0.91	4	(1.9)	5	2.37
Moderate or severe impairment	1	(2.2)	1	2.28	2	(3.5)	2	3.71
Vaginal infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Varicella								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral infection								
Normal	2	(0.9)	2	0.90	3	(1.4)	3	1.36
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Viral pharyngitis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.4)	1	0.45	3	(1.4)	3	1.36
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal candidiasis								
Normal	2	(0.9)	3	1.35	4	(1.8)	4	1.82
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal mycotic infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Injury, poisoning and procedural complications								
All								
Normal	26	(11.6)	28	12.64	12	(5.4)	15	6.81
Mild impairment	30	(13.5)	33	14.96	21	(9.9)	24	11.38
Moderate or severe impairment	4	(8.9)	4	9.13	7	(12.3)	13	24.13
Accidental overdose								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Animal bite								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Ankle fracture								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Bone contusion								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burn oral cavity								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Burns first degree								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cervical vertebral fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Chillblains								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Contusion								
Normal	2	(0.9)	3	1.35	1	(0.5)	1	0.45
Mild impairment	3	(1.3)	3	1.36	3	(1.4)	3	1.42
Moderate or severe impairment	0				1	(1.8)	1	1.86
Deafness traumatic								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endotracheal intubation complication								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Eye injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Fall								
Normal	4	(1.8)	4	1.81	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Fibula fracture								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Foot fracture								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Hand fracture								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Heat illness								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	2	3.71
Hip fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Injury								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Joint injury								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Ligament sprain								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Limb injury								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lower limb fracture								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Meniscus injury								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Muscle strain								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Overdose								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Post procedural fistula								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural haemorrhage								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Post procedural hypothyroidism								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural stroke								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Post procedural swelling								
Normal	0				1	(0.5)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Procedural pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Radius fracture								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Rib fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Scar								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Skin abrasion								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Skin laceration								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	1	(0.4)	1	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Soft tissue injury								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Thermal burn								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Tooth fracture								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Traumatic haematoma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Underdose								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Vaccination complication								
Normal	3	(1.3)	3	1.35	3	(1.4)	5	2.27
Mild impairment	7	(3.1)	7	3.17	6	(2.8)	8	3.79
Moderate or severe impairment	0				4	(7.0)	6	11.14
Wound								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Wrist fracture								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Investigations								
All								
Normal	6	(2.7)	6	2.71	10	(4.5)	11	5.00
Mild impairment	13	(5.8)	16	7.25	9	(4.2)	9	4.27
Moderate or severe impairment	2	(4.4)	2	4.57	2	(3.5)	2	3.71
Alanine aminotransferase increased								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Aspartate aminotransferase increased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Blood cholesterol increased								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood creatine increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Blood creatine phosphokinase increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Blood glucose increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Blood pressure decreased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Blood pressure increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Blood triglycerides increased								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body temperature increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cardiac stress test abnormal								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Electrocardiogram repolarisation abnormality								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Glycosylated haemoglobin increased								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemoglobin decreased								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic enzyme increased								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
International normalised ratio abnormal								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
International normalised ratio decreased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
International normalised ratio increased								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	0			
Moderate or severe impairment	0				0			
Lipids increased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Red blood cell count decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
SARS-CoV-2 test positive								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Transferrin saturation decreased								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Weight decreased								
Normal	0				1	(0.5)	1	0.45
Mild impairment	3	(1.3)	3	1.36	0			
Moderate or severe impairment	0				0			
Weight increased								
Normal	1	(0.4)	1	0.45	6	(2.7)	6	2.72
Mild impairment	3	(1.3)	3	1.36	4	(1.9)	4	1.90
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Metabolism and nutrition disorders								
All								
Normal	18	(8.0)	21	9.48	18	(8.1)	21	9.54
Mild impairment	18	(8.1)	20	9.07	23	(10.8)	30	14.22
Moderate or severe impairment	5	(11.1)	6	13.70	5	(8.8)	9	16.71
Appetite disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Decreased appetite								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Dehydration								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Diabetes mellitus								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Dyslipidaemia								
Normal	7	(3.1)	7	3.16	4	(1.8)	4	1.82
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Electrolyte imbalance								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fluid retention								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gout								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				2	(3.5)	2	3.71
Hypercholesterolaemia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperglycaemia								
Normal	0				5	(2.3)	5	2.27
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperkalaemia								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	2	(4.4)	3	6.85	1	(1.8)	1	1.86
Hyperlipidaemia								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Hypertriglyceridaemia								
Normal	3	(1.3)	3	1.35	2	(0.9)	2	0.91
Mild impairment	3	(1.3)	3	1.36	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Hyperuricaemia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hypoglycaemia								
Normal	3	(1.3)	4	1.81	1	(0.5)	4	1.82
Mild impairment	1	(0.4)	1	0.45	7	(3.3)	11	5.21
Moderate or severe impairment	0				1	(1.8)	5	9.28
Hypokalaemia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Increased appetite								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Iron deficiency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Malnutrition								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Metabolic disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Obesity								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Vitamin D deficiency								
Normal	0				1	(0.5)	1	0.45
Mild impairment	4	(1.8)	4	1.81	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Zinc deficiency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	45	(20.1)	74	33.41	36	(16.2)	54	24.52
Mild impairment	46	(20.6)	71	32.18	44	(20.7)	61	28.91
Moderate or severe impairment	8	(17.8)	11	25.11	12	(21.1)	18	33.42
Arthralgia								
Normal	10	(4.5)	13	5.87	7	(3.2)	7	3.18
Mild impairment	9	(4.0)	10	4.53	5	(2.3)	6	2.84
Moderate or severe impairment	4	(8.9)	4	9.13	5	(8.8)	6	11.14
Arthritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Axillary mass								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Back disorder								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Back pain								
Normal	8	(3.6)	9	4.06	9	(4.1)	10	4.54
Mild impairment	17	(7.6)	18	8.16	12	(5.6)	12	5.69
Moderate or severe impairment	2	(4.4)	2	4.57	3	(5.3)	3	5.57
Bone cyst								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bursitis								
Normal	0				2	(0.9)	2	0.91
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chondropathy								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Coccydynia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Costochondritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dupuytren's contracture								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Exostosis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fibromyalgia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Fistula								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Flank pain								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Groin pain								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Intervertebral disc disorder								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Intervertebral disc protrusion								
Normal	0				2	(0.9)	3	1.36
Mild impairment	4	(1.8)	5	2.27	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Joint effusion								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Joint swelling								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Limb deformity								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Lumbar spinal stenosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mastication disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	2	3.71
Muscle contracture								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Muscle spasms								
Normal	3	(1.3)	3	1.35	1	(0.5)	1	0.45
Mild impairment	4	(1.8)	4	1.81	3	(1.4)	3	1.42
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Muscular weakness								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Musculoskeletal chest pain								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Musculoskeletal pain								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Musculoskeletal stiffness								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Myalgia								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Myositis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neck pain								
Normal	4	(1.8)	4	1.81	5	(2.3)	5	2.27
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Osteoarthritis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	6	(2.7)	8	3.61	5	(2.3)	6	2.72
Mild impairment	6	(2.7)	6	2.72	4	(1.9)	4	1.90
Moderate or severe impairment	0				0			
Osteochondrosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Osteopenia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Pain in extremity								
Normal	7	(3.1)	7	3.16	4	(1.8)	4	1.82
Mild impairment	6	(2.7)	7	3.17	7	(3.3)	10	4.74
Moderate or severe impairment	2	(4.4)	2	4.57	0			
Periarthritis								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	1	(2.2)	1	2.28	2	(3.5)	2	3.71
Plantar fasciitis								
Normal	1	(0.4)	2	0.90	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Polyarthritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rotator cuff syndrome								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Spinal osteoarthritis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Spinal pain								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Spinal stenosis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				1	(1.8)	1	1.86
Synovial cyst								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Tendonitis								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Tenosynovitis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				3	(1.4)	4	1.90
Moderate or severe impairment	0				1	(1.8)	1	1.86
Tenosynovitis stenosans								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Trigger finger								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	4	1.90
Moderate or severe impairment	0				0			
Vertebral osteophyte								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	4	(1.8)	4	1.81	0			
Mild impairment	5	(2.2)	7	3.17	3	(1.4)	7	3.32
Moderate or severe impairment	2	(4.4)	2	4.57	2	(3.5)	2	3.71
Acrochordon								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Basal cell carcinoma								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Colon cancer								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Dysplastic naevus								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Glioblastoma multiforme								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hepatocellular carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Malignant melanoma in situ								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Metastases to liver								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Neoplasm skin								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Oral fibroma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Ovarian cancer metastatic								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Pancreatic neoplasm								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Prostate cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Renal cell carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Salivary gland neoplasm								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Seborrhoeic keratosis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	1	(0.4)	2	0.91	0			
Moderate or severe impairment	0				0			
Uterine leiomyoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Nervous system disorders								
All								
Normal	26	(11.6)	35	15.80	24	(10.8)	29	13.17
Mild impairment	34	(15.2)	46	20.85	32	(15.0)	43	20.38
Moderate or severe impairment	5	(11.1)	6	13.70	11	(19.3)	13	24.13
Ageusia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anosmia								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Balance disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Brain injury								
Normal	0				1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burning sensation								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Carotid arteriosclerosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Carpal tunnel syndrome								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	2	(0.9)	2	0.91	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Cerebral atrophy								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebral haemorrhage								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cerebrovascular disorder								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cervical radiculopathy								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic neuropathy								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Dizziness								
Normal	4	(1.8)	4	1.81	4	(1.8)	4	1.82
Mild impairment	7	(3.1)	11	4.99	7	(3.3)	8	3.79
Moderate or severe impairment	1	(2.2)	1	2.28	3	(5.3)	3	5.57
Dizziness postural								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dysgeusia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Headache								
Normal	8	(3.6)	8	3.61	6	(2.7)	6	2.72
Mild impairment	6	(2.7)	8	3.63	9	(4.2)	16	7.58
Moderate or severe impairment	2	(4.4)	2	4.57	2	(3.5)	2	3.71
Hypoaesthesia								
Normal	2	(0.9)	4	1.81	0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	2	(3.5)	3	5.57
Lethargy								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Lumbar radiculopathy								
Normal	0				2	(0.9)	2	0.91
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Memory impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Mental impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Migraine								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Neuralgia								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuroglycopenia								
Normal	1	(0.4)	1	0.45	1	(0.5)	3	1.36
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuropathy peripheral								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Paraesthesia								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Parkinsonian gait								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Presyncope								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				2	(3.5)	2	3.71
Sciatica								
Normal	1	(0.4)	1	0.45	3	(1.4)	4	1.82
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	3	1.42
Moderate or severe impairment	0				0			
Somnolence								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Syncope								
Normal	4	(1.8)	4	1.81	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Tension headache								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Thrombotic stroke								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Transient ischaemic attack								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47

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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Tremor								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	3	(1.3)	4	1.81	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Trigeminal neuralgia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Psychiatric disorders								
All								
Normal	4	(1.8)	4	1.81	9	(4.1)	9	4.09
Mild impairment	9	(4.0)	10	4.53	1	(0.5)	1	0.47
Moderate or severe impairment	2	(4.4)	2	4.57	0			
Anxiety								
Normal	0				2	(0.9)	2	0.91
Mild impairment	3	(1.3)	3	1.36	0			
Moderate or severe impairment	0				0			
Bruxism								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Depressed mood								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Depression								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Insomnia								
Normal	1	(0.4)	1	0.45	2	(0.9)	2	0.91
Mild impairment	4	(1.8)	4	1.81	1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Mood swings								
Normal	0				1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nightmare								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Persistent depressive disorder								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sleep disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Renal and urinary disorders								
All								
Normal	5	(2.2)	7	3.16	3	(1.4)	3	1.36
Mild impairment	4	(1.8)	6	2.72	12	(5.6)	12	5.69
Moderate or severe impairment	5	(11.1)	5	11.41	5	(8.8)	7	12.99
Acute kidney injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Calculus urinary								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Chronic kidney disease								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				2	(3.5)	2	3.71
Diabetic nephropathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Dysuria								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Haematuria								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				3	(1.4)	3	1.42
Moderate or severe impairment	0				0			
Microalbuminuria								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephrolithiasis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Nocturia								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Pollakiuria								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Pyelocaliectasis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal colic								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal cyst								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal impairment								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	2	(4.4)	2	4.57	1	(1.8)	1	1.86
Ureterolithiasis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Urinary incontinence								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Urinary retention								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Urinary tract obstruction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Urine odour abnormal								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Reproductive system and breast disorders								
All								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	5	(2.2)	5	2.27	4	(1.9)	5	2.37
Moderate or severe impairment	3	(6.7)	3	6.85	1	(1.8)	2	3.71
Atrophic vulvovaginitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Breast mass								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Breast pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Erectile dysfunction								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Galactorrhoea								
Normal	0				1	(0.5)	1	0.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menopausal symptoms								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Ovarian cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Penile rash								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Pruritus genital								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Uterine polyp								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Uterine prolapse								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal dryness								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal pruritus								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	24	(10.7)	32	14.45	17	(7.7)	23	10.45
Mild impairment	19	(8.5)	24	10.88	16	(7.5)	22	10.43
Moderate or severe impairment	2	(4.4)	3	6.85	5	(8.8)	7	12.99

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acquired diaphragmatic eventration								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acute pulmonary oedema								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Acute respiratory failure								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Allergic bronchitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Asthma								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bronchiectasis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bronchitis chronic								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Chronic obstructive pulmonary disease								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Cough								
Normal	8	(3.6)	8	3.61	3	(1.4)	3	1.36
Mild impairment	2	(0.9)	2	0.91	5	(2.3)	6	2.84
Moderate or severe impairment	0				0			
Dyspnoea								
Normal	0				3	(1.4)	3	1.36
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Dyspnoea exertional								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Emphysema								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epistaxis								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.95
Moderate or severe impairment	0				0			
Haemoptysis								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Interstitial lung disease								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Laryngeal cyst								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal congestion								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Nasal dryness								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oropharyngeal pain								
Normal	5	(2.2)	5	2.26	3	(1.4)	3	1.36
Mild impairment	4	(1.8)	4	1.81	3	(1.4)	4	1.90
Moderate or severe impairment	1	(2.2)	2	4.57	1	(1.8)	1	1.86
Paranasal sinus discomfort								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pleural effusion								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Pleuritic pain								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Productive cough								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Pulmonary embolism								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Pulmonary fibrosis								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary mass								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Respiratory disorder								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Respiratory failure								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rhinitis allergic								
Normal	0				1	(0.5)	5	2.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rhinorrhoea								
Normal	3	(1.3)	3	1.35	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Sinus congestion								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Sinus pain								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.91	0			
Moderate or severe impairment	0				0			
Sleep apnoea syndrome								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Sneezing								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Throat irritation								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Upper-airway cough syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	15	(6.7)	15	6.77	14	(6.3)	16	7.27
Mild impairment	22	(9.9)	24	10.88	20	(9.4)	27	12.80
Moderate or severe impairment	5	(11.1)	5	11.41	8	(14.0)	12	22.28
Actinic keratosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Alopecia								
Normal	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Alopecia areata								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angioedema								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Asteatosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Blister								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				1	(1.8)	1	1.86
Cold urticaria								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Dermal cyst								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Dermatitis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Dermatitis allergic								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermatitis contact								
Normal	2	(0.9)	2	0.90	2	(0.9)	2	0.91
Mild impairment	2	(0.9)	3	1.36	3	(1.4)	3	1.42
Moderate or severe impairment	1	(2.2)	1	2.28	1	(1.8)	1	1.86
Diabetic foot								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Drug eruption								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Dry skin								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Ecchymosis								
Normal	0				2	(0.9)	2	0.91
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eczema								
Normal	2	(0.9)	2	0.90	0			
Mild impairment	3	(1.3)	3	1.36	0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Erythema								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Granuloma annulare								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemorrhage subcutaneous								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Hyperhidrosis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hyperkeratosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Ingrowing nail								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Lentigo								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipodystrophy acquired								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Lipohypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Macule								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Miliaria								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				2	(3.5)	2	3.71
Myxoid cyst								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Night sweats								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Pruritus								
Normal	0				1	(0.5)	1	0.45
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				2	(3.5)	2	3.71
Psoriasis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.91	0			
Moderate or severe impairment	0				0			
Purpura								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Rash								
Normal	0				3	(1.4)	3	1.36
Mild impairment	2	(0.9)	2	0.91	3	(1.4)	3	1.42
Moderate or severe impairment	0				0			
Skin exfoliation								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Skin fissures								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Skin irritation								
Normal	0				0			
Mild impairment	2	(0.9)	3	1.36	0			
Moderate or severe impairment	0				0			
Skin lesion								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Skin ulcer								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Urticaria								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				1	(1.8)	1	1.86
Urticaria contact								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urticaria thermal								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Knee operation								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Large intestinal polypectomy								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Removal of foreign body								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Vascular disorders								
All								
Normal	14	(6.3)	17	7.68	5	(2.3)	8	3.63
Mild impairment	14	(6.3)	16	7.25	16	(7.5)	17	8.06
Moderate or severe impairment	4	(8.9)	4	9.13	4	(7.0)	4	7.43
Aortic arteriosclerosis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Aortic stenosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Arteriosclerosis								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Blood pressure inadequately controlled								
Normal	0				1	(0.5)	1	0.45
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Brachiocephalic arteriosclerosis								
Normal	1	(0.4)	1	0.45	1	(0.5)	1	0.45
Mild impairment	0				2	(0.9)	2	0.95
Moderate or severe impairment	0				0			
Flushing								
Normal	1	(0.4)	1	0.45	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematoma								
Normal	0				1	(0.5)	1	0.45
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hypertension								
Normal	6	(2.7)	6	2.71	2	(0.9)	3	1.36
Mild impairment	5	(2.2)	5	2.27	5	(2.3)	5	2.37
Moderate or severe impairment	2	(4.4)	2	4.57	3	(5.3)	3	5.57
Hypertensive crisis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Hypertensive urgency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Hypotension								
Normal	3	(1.3)	3	1.35	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.86
Iliac artery stenosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Intermittent claudication								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Macroangiopathy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral arterial occlusive disease								
Normal	1	(0.4)	2	0.90	1	(0.5)	1	0.45
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Peripheral artery occlusion								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Peripheral artery stenosis								
Normal	1	(0.4)	2	0.90	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Peripheral coldness								
Normal	0				0			
Mild impairment	3	(1.3)	3	1.36	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			
Peripheral vascular disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Peripheral venous disease								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.47
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Superficial vein thrombosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	0			
Moderate or severe impairment	0				0			
Thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	2.28	0			
Varicose vein								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.45	1	(0.5)	1	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.46 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	94				109			
Mild impairment	134				108			
Moderate impairment	34				46			
PYE (years)								
Normal	55.36				62.74			
Mild impairment	80.04				63.33			
Moderate impairment	19.84				26.70			
Events								
Normal	58	(61.7)	165	298.05	52	(47.7)	129	205.63
Mild impairment	80	(59.7)	248	309.83	59	(54.6)	133	210.00
Moderate impairment	23	(67.6)	53	267.08	23	(50.0)	66	247.14
Blood and lymphatic system disorders								
All								
Normal	1	(1.1)	3	5.42	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Anaemia								
Normal	1	(1.1)	3	5.42	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Thrombocytosis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Normal	2	(2.1)	3	5.42	0			
Mild impairment	3	(2.2)	4	5.00	1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Acute myocardial infarction								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
Atrial fibrillation								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Bradycardia								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Cardiac failure congestive								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Cardiac flutter								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Coronary artery disease								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Myocardial infarction								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Supraventricular tachycardia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	2	(2.1)	2	3.61	2	(1.8)	2	3.19
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	2	(5.9)	2	10.08	1	(2.2)	1	3.74
Deafness unilateral								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Ear pain								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoacusis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tinnitus								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Vertigo								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	2	(5.9)	2	10.08	0			
Endocrine disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	0				2	(1.8)	2	3.19
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Adrenocortical insufficiency acute								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Hypothyroidism								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Inappropriate antidiuretic hormone secretion								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Eye disorders								
All								
Normal	9	(9.6)	11	19.87	14	(12.8)	17	27.10
Mild impairment	15	(11.2)	17	21.24	7	(6.5)	9	14.21
Moderate impairment	3	(8.8)	3	15.12	4	(8.7)	4	14.98
Astigmatism								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Cataract								
Normal	1	(1.1)	1	1.81	3	(2.8)	3	4.78
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
Cataract nuclear								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Conjunctival haemorrhage								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Diabetic retinal oedema								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
Diabetic retinopathy								
Normal	3	(3.2)	4	7.23	11	(10.1)	12	19.13

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	5	(3.7)	5	6.25	4	(3.7)	4	6.32
Moderate impairment	2	(5.9)	2	10.08	1	(2.2)	1	3.74
Dry age-related macular degeneration								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Dry eye								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Epiretinal membrane								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Eye irritation								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Glaucoma								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Lacrimation increased								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Macular oedema								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Myopia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Non-proliferative retinopathy								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Ocular hyperaemia								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ocular hypertension								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Presbyopia								
Normal	0				0			
Mild impairment	0				2	(1.9)	2	3.16
Moderate impairment	0				0			
Retinal exudates								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Retinal haemorrhage								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Retinal vein occlusion								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Vision blurred								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Visual acuity reduced								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Gastrointestinal disorders								
All								
Normal	12	(12.8)	21	37.93	17	(15.6)	22	35.07
Mild impairment	18	(13.4)	31	38.73	9	(8.3)	10	15.79
Moderate impairment	8	(23.5)	8	40.31	6	(13.0)	10	37.45
Abdominal pain								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Abdominal pain lower								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Abdominal pain upper								
Normal	1	(1.1)	3	5.42	2	(1.8)	2	3.19
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Chronic gastritis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Constipation								
Normal	0				0			
Mild impairment	3	(2.2)	6	7.50	0			
Moderate impairment	1	(2.9)	1	5.04	0			
Dental caries								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				2	(4.3)	2	7.49
Diarrhoea								
Normal	3	(3.2)	3	5.42	4	(3.7)	4	6.38
Mild impairment	8	(6.0)	11	13.74	3	(2.8)	3	4.74
Moderate impairment	3	(8.8)	3	15.12	2	(4.3)	2	7.49
Diverticulum								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dyspepsia								
Normal	2	(2.1)	2	3.61	1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Flatulence								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Food poisoning								
Normal	0				1	(0.9)	2	3.19
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Gastric dysplasia								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Gastric mucosal hypertrophy								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastric polyps								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Gastritis								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Gastrointestinal angiodysplasia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Gastrooesophageal reflux disease								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			
Gingival bleeding								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Haemorrhoids								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Hiatus hernia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Hyperaesthesia teeth								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Intra-abdominal haematoma								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Large intestine polyp								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Nausea								
Normal	4	(4.3)	4	7.23	3	(2.8)	3	4.78
Mild impairment	3	(2.2)	3	3.75	0			
Moderate impairment	0				3	(6.5)	3	11.23

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pancreatic pseudocyst								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Periodontal disease								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Tongue rough								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Toothache								
Normal	0				1	(0.9)	3	4.78
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Vomiting								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	2	(1.5)	2	2.50	2	(1.9)	2	3.16
Moderate impairment	0				1	(2.2)	1	3.74
General disorders and administration site conditions								
All								
Normal	8	(8.5)	13	23.48	9	(8.3)	10	15.94
Mild impairment	15	(11.2)	21	26.24	8	(7.4)	8	12.63
Moderate impairment	2	(5.9)	2	10.08	2	(4.3)	3	11.23
Asthenia								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Chest discomfort								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Chest pain								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Chills								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Condition aggravated								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Fatigue								
Normal	1	(1.1)	2	3.61	2	(1.8)	2	3.19
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Hunger								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Influenza like illness								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Injection site reaction								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
Injection site swelling								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Malaise								
Normal	1	(1.1)	1	1.81	1	(0.9)	2	3.19
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Medical device site bruise								
Normal	1	(1.1)	2	3.61	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Medical device site dermatitis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Medical device site erythema								
Normal	2	(2.1)	2	3.61	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Medical device site pruritus								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Medical device site rash								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Medical device site reaction								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Oedema peripheral								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Pain								
Normal	0				1	(0.9)	1	1.59
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Pyrexia								
Normal	0				4	(3.7)	4	6.38
Mild impairment	5	(3.7)	5	6.25	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	1	(2.2)	1	3.74
Vaccination site pain								
Normal	0				0			
Mild impairment	2	(1.5)	3	3.75	2	(1.9)	2	3.16
Moderate impairment	1	(2.9)	1	5.04	1	(2.2)	1	3.74
Hepatobiliary disorders								
All								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	1	(2.9)	1	5.04	0			
Alcoholic liver disease								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Gallbladder polyp								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Hepatic cirrhosis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	1	(1.1)	1	1.81	3	(2.8)	3	4.78
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				2	(4.3)	2	7.49
Allergy to arthropod bite								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Allergy to arthropod sting								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Anaphylactic reaction								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Seasonal allergy								
Normal	1	(1.1)	1	1.81	2	(1.8)	2	3.19
Mild impairment	0				0			
Moderate impairment	0				0			
Infections and infestations								
All								
Normal	23	(24.5)	38	68.64	18	(16.5)	25	39.85
Mild impairment	44	(32.8)	50	62.47	24	(22.2)	34	53.69
Moderate impairment	9	(26.5)	10	50.39	7	(15.2)	7	26.21
Abscess limb								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Anal abscess								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Bronchitis								
Normal	0				0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Campylobacter gastroenteritis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cellulitis								
Normal	1	(1.1)	1	1.81	1	(0.9)	2	3.19
Mild impairment	0				0			
Moderate impairment	0				0			
Conjunctivitis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
COVID-19								
Normal	3	(3.2)	3	5.42	4	(3.7)	4	6.38
Mild impairment	3	(2.2)	3	3.75	2	(1.9)	2	3.16
Moderate impairment	3	(8.8)	3	15.12	1	(2.2)	1	3.74
COVID-19 pneumonia								
Normal	0				0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Cystitis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	2	3.16
Moderate impairment	0				0			
Ear infection								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Enteritis infectious								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Eye infection								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Folliculitis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Fungal infection								
Normal	1	(1.1)	2	3.61	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fungal skin infection								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis								
Normal	2	(2.1)	2	3.61	1	(0.9)	1	1.59
Mild impairment	2	(1.5)	2	2.50	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			
Gastrointestinal infection								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Gingivitis								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Helicobacter infection								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Herpes zoster								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				2	(1.9)	2	3.16
Moderate impairment	0				0			
Influenza								
Normal	0				3	(2.8)	4	6.38
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Kidney infection								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Localised infection								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Nasopharyngitis								
Normal	9	(9.6)	12	21.68	2	(1.8)	3	4.78
Mild impairment	13	(9.7)	16	19.99	7	(6.5)	10	15.79
Moderate impairment	0				1	(2.2)	1	3.74
Onychomycosis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Otitis media								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	2	(1.5)	2	2.50	1	(0.9)	1	1.58
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paraspinal abscess								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Peritonsillar abscess								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Pneumonia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Pulpitis dental								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Pustule								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Rhinitis								
Normal	0				0			
Mild impairment	0				1	(0.9)	3	4.74
Moderate impairment	0				0			
Sinusitis								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	2	(1.9)	2	3.16
Moderate impairment	0				0			
Soft tissue infection								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Subcutaneous abscess								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Tinea pedis								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Tinea versicolour								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tonsillitis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Tooth abscess								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth infection								
Normal	1	(1.1)	2	3.61	1	(0.9)	1	1.59
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Upper respiratory tract infection								
Normal	2	(2.1)	2	3.61	3	(2.8)	3	4.78
Mild impairment	6	(4.5)	9	11.24	0			
Moderate impairment	0				1	(2.2)	1	3.74
Urinary tract infection								
Normal	3	(3.2)	3	5.42	0			
Mild impairment	0				2	(1.9)	2	3.16
Moderate impairment	1	(2.9)	2	10.08	1	(2.2)	1	3.74
Vaginal infection								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Varicella zoster virus infection								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Vulvitis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Vulvovaginal candidiasis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Wound infection								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	6	(6.4)	7	12.64	6	(5.5)	6	9.56

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	17	(12.7)	26	32.48	11	(10.2)	12	18.95
Moderate impairment	4	(11.8)	6	30.24	5	(10.9)	8	29.96
Accidental overdose								
Normal	0				0			
Mild impairment	3	(2.2)	3	3.75	0			
Moderate impairment	1	(2.9)	1	5.04	0			
Arthropod bite								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Bone contusion								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Contusion								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Craniocerebral injury								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Face injury								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Facial bones fracture								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fall								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	4	(3.0)	4	5.00	1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Foot fracture								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Hand fracture								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Heat illness								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Intentional overdose								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Joint injury								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Ligament sprain								
Normal	0				1	(0.9)	1	1.59
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Limb injury								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	2	7.49
Muscle contusion								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Muscle injury								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Overdose								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Rib fracture								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Road traffic accident								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Skin abrasion								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin laceration								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	1	(2.9)	1	5.04	0			
Stab wound								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Subcutaneous haematoma								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Tendon injury								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Tendon rupture								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Thermal burn								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Tibia fracture								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Underdose								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Vaccination complication								
Normal	2	(2.1)	3	5.42	0			
Mild impairment	1	(0.7)	4	5.00	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	2	(4.3)	2	7.49
Wound								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Wrist fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
Normal	2	(2.1)	2	3.61	1	(0.9)	1	1.59
Mild impairment	0				2	(1.9)	3	4.74
Moderate impairment	3	(8.8)	3	15.12	0			
Alanine aminotransferase increased								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood creatinine increased								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	2	(5.9)	2	10.08	0			
Blood potassium increased								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Intraocular pressure increased								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Liver function test abnormal								
Normal	0				0			
Mild impairment	0				1	(0.9)	2	3.16
Moderate impairment	0				0			
SARS-CoV-2 test positive								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Normal	4	(4.3)	4	7.23	3	(2.8)	3	4.78
Mild impairment	1	(0.7)	1	1.25	6	(5.6)	11	17.37
Moderate impairment	2	(5.9)	2	10.08	2	(4.3)	2	7.49
Abnormal weight gain								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperammonaemia								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Hypercholesterolaemia								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Hyperglycaemia								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			
Hyperkalaemia								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			
Hyperlipidaemia								
Normal	1	(1.1)	1	1.81	2	(1.8)	2	3.19
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Hyperuricaemia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				2	(1.9)	7	11.05
Moderate impairment	0				1	(2.2)	1	3.74
Musculoskeletal and connective tissue disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	17	(18.1)	24	43.35	14	(12.8)	21	33.47
Mild impairment	19	(14.2)	32	39.98	11	(10.2)	17	26.84
Moderate impairment	2	(5.9)	4	20.16	4	(8.7)	7	26.21
Arthralgia								
Normal	2	(2.1)	2	3.61	6	(5.5)	7	11.16
Mild impairment	3	(2.2)	3	3.75	3	(2.8)	5	7.89
Moderate impairment	1	(2.9)	2	10.08	1	(2.2)	1	3.74
Arthritis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Axillary mass								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Back pain								
Normal	5	(5.3)	5	9.03	3	(2.8)	4	6.38
Mild impairment	2	(1.5)	2	2.50	5	(4.6)	5	7.89
Moderate impairment	0				3	(6.5)	4	14.98
Bursitis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Flank pain								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Intervertebral disc disorder								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Intervertebral disc protrusion								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Muscle spasms								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	7	(5.2)	9	11.24	1	(0.9)	1	1.58
Moderate impairment	1	(2.9)	1	5.04	0			
Musculoskeletal stiffness								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myalgia								
Normal	1	(1.1)	1	1.81	2	(1.8)	2	3.19
Mild impairment	3	(2.2)	3	3.75	0			
Moderate impairment	0				0			
Neck pain								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Osteoarthritis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Osteoporosis								
Normal	0				0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Pain in extremity								
Normal	2	(2.1)	2	3.61	2	(1.8)	2	3.19
Mild impairment	1	(0.7)	1	1.25	3	(2.8)	4	6.32
Moderate impairment	0				0			
Periarthritis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Plantar fasciitis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Polymyalgia rheumatica								
Normal	0				1	(0.9)	3	4.78
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Rheumatoid arthritis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Rotator cuff syndrome								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Soft tissue swelling								
Normal	1	(1.1)	3	5.42	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
Normal	1	(1.1)	2	3.61	0			
Mild impairment	1	(0.7)	2	2.50	0			
Moderate impairment	0				0			
Tendonitis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	3	3.75	0			
Moderate impairment	0				0			
Tenosynovitis								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Trigger finger								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	3	(2.8)	3	4.74
Moderate impairment	1	(2.9)	1	5.04	1	(2.2)	1	3.74
Breast cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Chronic myeloid leukaemia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Colon adenoma								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Colon cancer stage II								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Gastric cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Lymphangioma								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Pancreatic carcinoma metastatic								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Nervous system disorders								
All								
Normal	14	(14.9)	17	30.71	7	(6.4)	8	12.75
Mild impairment	11	(8.2)	22	27.48	9	(8.3)	12	18.95
Moderate impairment	2	(5.9)	3	15.12	9	(19.6)	14	52.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Autonomic nervous system imbalance								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Burning sensation								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Carotid artery aneurysm								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Carpal tunnel syndrome								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cerebral infarction								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Cervicobrachial syndrome								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Diabetic neuropathy								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Dizziness								
Normal	0				2	(1.8)	3	4.78
Mild impairment	3	(2.2)	4	5.00	2	(1.9)	4	6.32
Moderate impairment	1	(2.9)	1	5.04	5	(10.9)	6	22.47
Facial paralysis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Headache								
Normal	7	(7.4)	9	16.26	4	(3.7)	4	6.38
Mild impairment	7	(5.2)	11	13.74	2	(1.9)	2	3.16
Moderate impairment	0				3	(6.5)	4	14.98
Hypoaesthesia								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Migraine								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Neuralgia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Neuropathy peripheral								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Peripheral paralysis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Piriformis syndrome								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Restless legs syndrome								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Sciatica								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				1	(2.2)	1	3.74
Somnolence								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Syncope								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Tension headache								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thalamic infarction								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Thrombotic stroke								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Tremor								
Normal	0				0			
Mild impairment	0				2	(1.9)	2	3.16
Moderate impairment	0				0			
Psychiatric disorders								
All								
Normal	1	(1.1)	2	3.61	1	(0.9)	1	1.59
Mild impairment	2	(1.5)	2	2.50	4	(3.7)	4	6.32
Moderate impairment	1	(2.9)	1	5.04	0			
Adjustment disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Depression								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				2	(1.9)	2	3.16
Moderate impairment	0				0			
Insomnia								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Major depression								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Sleep disorder								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Renal and urinary disorders								
All								
Normal	2	(2.1)	2	3.61	0			
Mild impairment	5	(3.7)	7	8.75	0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bladder prolapse								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Diabetic nephropathy								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Hydronephrosis								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Nephrotic syndrome								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Pollakiuria								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Polyuria								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Renal cyst								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Renal impairment								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Urethral stenosis								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Urine odour abnormal								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	1	(1.1)	1	1.81	2	(1.8)	2	3.19
Mild impairment	3	(2.2)	3	3.75	0			
Moderate impairment	0				0			
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Cervical polyp								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Erectile dysfunction								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Prostatitis								
Normal	1	(1.1)	1	1.81	1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Pruritus genital								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	4	(4.3)	8	14.45	1	(0.9)	1	1.59
Mild impairment	8	(6.0)	16	19.99	2	(1.9)	3	4.74
Moderate impairment	3	(8.8)	5	25.20	1	(2.2)	1	3.74
Acute respiratory failure								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Chronic obstructive pulmonary disease								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	1	(2.9)	1	5.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cough								
Normal	1	(1.1)	2	3.61	0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Epistaxis								
Normal	2	(2.1)	2	3.61	0			
Mild impairment	1	(0.7)	5	6.25	0			
Moderate impairment	0				0			
Nasal congestion								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Nasal obstruction								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Nasal septum deviation								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Oropharyngeal pain								
Normal	0				1	(0.9)	1	1.59
Mild impairment	0				1	(0.9)	2	3.16
Moderate impairment	1	(2.9)	1	5.04	0			
Productive cough								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	1	(0.7)	1	1.25	1	(0.9)	1	1.58
Moderate impairment	0				0			
Respiratory failure								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Rhinorrhoea								
Normal	2	(2.1)	2	3.61	0			
Mild impairment	3	(2.2)	5	6.25	0			
Moderate impairment	0				1	(2.2)	1	3.74
Sleep apnoea syndrome								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Sneezing								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
Normal	3	(3.2)	3	5.42	1	(0.9)	1	1.59
Mild impairment	9	(6.7)	10	12.49	2	(1.9)	2	3.16
Moderate impairment	1	(2.9)	1	5.04	3	(6.5)	3	11.23
Alopecia								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Blister								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dermal cyst								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Dermatitis								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Eczema								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Hyperhidrosis								
Normal	0				1	(0.9)	1	1.59
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			
Miliaria								
Normal	0				0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Neurodermatitis								
Normal	0				0			
Mild impairment	0				1	(0.9)	1	1.58
Moderate impairment	0				0			
Pruritus								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rash								
Normal	0				0			
Mild impairment	3	(2.2)	3	3.75	0			
Moderate impairment	0				1	(2.2)	1	3.74
Rash papular								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.9)	1	5.04	0			
Urticaria								
Normal	1	(1.1)	1	1.81	0			
Mild impairment	2	(1.5)	2	2.50	0			
Moderate impairment	0				0			
Surgical and medical procedures								
All								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Toe amputation								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.2)	1	3.74
Vascular disorders								
All								
Normal	2	(2.1)	2	3.61	2	(1.8)	2	3.19
Mild impairment	3	(2.2)	3	3.75	3	(2.8)	3	4.74
Moderate impairment	0				0			
Hypertension								
Normal	2	(2.1)	2	3.61	2	(1.8)	2	3.19
Mild impairment	2	(1.5)	2	2.50	3	(2.8)	3	4.74
Moderate impairment	0				0			
Orthostatic hypotension								
Normal	0				0			
Mild impairment	1	(0.7)	1	1.25	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.47 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	123				127			
Mild impairment	121				120			
Moderate impairment	47				44			
PYE (years)								
Normal	70.74				72.58			
Mild impairment	69.79				70.23			
Moderate impairment	26.83				23.99			
Events								
Normal	64	(52.0)	186	262.92	57	(44.9)	223	307.26
Mild impairment	75	(62.0)	197	282.28	81	(67.5)	232	330.34
Moderate impairment	32	(68.1)	72	268.35	29	(65.9)	95	396.01
Blood and lymphatic system disorders								
All								
Normal	4	(3.3)	4	5.65	0			
Mild impairment	2	(1.7)	2	2.87	4	(3.3)	4	5.70
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Anaemia								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				1	(2.3)	1	4.17
Blood loss anaemia								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Eosinophilia								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Iron deficiency anaemia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Lymphadenopathy mediastinal								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	3	(2.4)	3	4.24	5	(3.9)	9	12.40
Mild impairment	3	(2.5)	4	5.73	5	(4.2)	5	7.12
Moderate impairment	1	(2.1)	1	3.73	4	(9.1)	8	33.35
Acute myocardial infarction								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Angina pectoris								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Aortic valve calcification								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Aortic valve sclerosis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Atrial enlargement								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Atrial fibrillation								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Bundle branch block left								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Bundle branch block right								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Cardiac failure								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	2	8.34
Cardiac failure congestive								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				2	(4.5)	3	12.51

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac perfusion defect								
Normal	0				1	(0.8)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
Coronary artery disease								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				1	(2.3)	1	4.17
Left atrial enlargement								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Left ventricular hypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Myocardial infarction								
Normal	0				0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				0			
Myocardial ischaemia								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Palpitations								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Pericarditis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Sinus bradycardia								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Tachycardia								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Corneal dystrophy								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Ear and labyrinth disorders								
All								
Normal	0				3	(2.4)	3	4.13
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Cerumen impaction								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Ear discomfort								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Middle ear inflammation								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Vertigo								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	2	(1.6)	2	2.83	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Adrenocortical insufficiency acute								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Hypogonadism								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypothyroidism								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Eye disorders								
All								
Normal	7	(5.7)	7	9.89	16	(12.6)	18	24.80
Mild impairment	17	(14.0)	23	32.96	17	(14.2)	25	35.60
Moderate impairment	2	(4.3)	3	11.18	5	(11.4)	14	58.36
Age-related macular degeneration								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Astigmatism								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Cataract								
Normal	0				1	(0.8)	1	1.38
Mild impairment	2	(1.7)	2	2.87	3	(2.5)	5	7.12
Moderate impairment	0				0			
Corneal erosion								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Diabetic retinal oedema								
Normal	1	(0.8)	1	1.41	1	(0.8)	2	2.76
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinopathy								
Normal	3	(2.4)	3	4.24	7	(5.5)	7	9.64
Mild impairment	8	(6.6)	10	14.33	6	(5.0)	6	8.54
Moderate impairment	1	(2.1)	1	3.73	2	(4.5)	2	8.34
Diplopia								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Eye discharge								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Eye inflammation								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Eye pain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Macular degeneration								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Macular oedema								
Normal	0				0			
Mild impairment	3	(2.5)	3	4.30	0			
Moderate impairment	0				1	(2.3)	1	4.17
Meibomianitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Open angle glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.8)	2	2.85
Moderate impairment	0				0			
Presbyopia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Retinal deposits								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal detachment								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Retinal drusen								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Retinal exudates								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Retinal haemorrhage								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Retinal scar								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Retinal vascular disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Retinopathy hypertensive								
Normal	1	(0.8)	1	1.41	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				0			
Vision blurred								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Visual impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	9	37.52
Vitreous detachment								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal disorders								
All								
Normal	11	(8.9)	19	26.86	18	(14.2)	25	34.45
Mild impairment	17	(14.0)	23	32.96	15	(12.5)	20	28.48
Moderate impairment	7	(14.9)	8	29.82	2	(4.5)	4	16.67
Abdominal discomfort								
Normal	0				0			
Mild impairment	0				1	(0.8)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Abdominal distension								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Abdominal pain								
Normal	1	(0.8)	1	1.41	3	(2.4)	4	5.51
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Abdominal pain upper								
Normal	0				2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Chronic gastritis								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Constipation								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				3	(2.5)	3	4.27
Moderate impairment	1	(2.1)	1	3.73	0			
Dental caries								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				3	(2.5)	3	4.27
Moderate impairment	0				0			
Diarrhoea								
Normal	3	(2.4)	4	5.65	5	(3.9)	5	6.89
Mild impairment	10	(8.3)	11	15.76	3	(2.5)	3	4.27
Moderate impairment	2	(4.3)	3	11.18	1	(2.3)	1	4.17
Eructation								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Faeces pale								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Food poisoning								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Gastrointestinal disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Gastrointestinal haemorrhage								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Gastrooesophageal reflux disease								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Gingival disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Hypoaesthesia oral								
Normal	0				0			
Mild impairment	1	(0.8)	3	4.30	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Nausea								
Normal	4	(3.3)	4	5.65	4	(3.1)	4	5.51
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Pancreatic duct dilatation								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Pancreatic failure								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Pancreatitis chronic								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Periodontal disease								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Proctalgia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Toothache								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	3	4.27
Moderate impairment	0				0			
Upper gastrointestinal haemorrhage								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Vomiting								
Normal	4	(3.3)	6	8.48	2	(1.6)	2	2.76
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	1	(2.1)	1	3.73	0			
General disorders and administration site conditions								
All								
Normal	9	(7.3)	14	19.79	7	(5.5)	7	9.64
Mild impairment	11	(9.1)	18	25.79	14	(11.7)	24	34.17
Moderate impairment	6	(12.8)	6	22.36	5	(11.4)	5	20.84
Asthenia								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				0			
Axillary pain								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Chest pain								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	2	(4.3)	2	7.45	0			
Cyst								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Discomfort								
Normal	0				0			
Mild impairment	0				1	(0.8)	8	11.39
Moderate impairment	0				0			
Facial pain								
Normal	0				1	(0.8)	1	1.38

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Fatigue								
Normal	3	(2.4)	3	4.24	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	2	2.87	0			
Moderate impairment	0				0			
Feeling abnormal								
Normal	0				0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				0			
Inflammation								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Injection site pain								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Injection site rash								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Injection site reaction								
Normal	0				0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				0			
Malaise								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Medical device site dermatitis								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Medical device site erythema								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Medical device site pain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Medical device site reaction								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	1	(2.1)	1	3.73	0			
Multiple organ dysfunction syndrome								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Oedema								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Oedema due to renal disease								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Oedema peripheral								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Pain								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	2	2.87	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Peripheral swelling								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Pyrexia								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	2	(1.7)	2	2.87	4	(3.3)	5	7.12
Moderate impairment	0				1	(2.3)	1	4.17
Thirst								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site inflammation								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site pain								
Normal	0				0			
Mild impairment	3	(2.5)	3	4.30	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Vaccination site pruritus								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Xerosis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatobiliary disorders								
All								
Normal	1	(0.8)	2	2.83	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	3	4.27
Moderate impairment	0				1	(2.3)	1	4.17
Biliary dyskinesia								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Cholecystitis chronic								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Gallbladder polyp								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Hepatic function abnormal								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Hepatic steatosis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Hepatomegaly								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperplastic cholecystopathy								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Liver disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	2	(1.6)	2	2.83	1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Drug hypersensitivity								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypersensitivity								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Seasonal allergy								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Infections and infestations								
All								
Normal	34	(27.6)	52	73.51	31	(24.4)	54	74.40
Mild impairment	35	(28.9)	42	60.18	34	(28.3)	47	66.92
Moderate impairment	18	(38.3)	23	85.72	14	(31.8)	19	79.20
Abscess								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Asymptomatic COVID-19								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Bacteraemia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Breast abscess								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Bronchitis								
Normal	3	(2.4)	3	4.24	2	(1.6)	2	2.76
Mild impairment	3	(2.5)	3	4.30	1	(0.8)	1	1.42
Moderate impairment	2	(4.3)	2	7.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Candida infection								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Cellulitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Cholecystitis infective								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Conjunctivitis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Coronavirus infection								
Normal	0				1	(0.8)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
COVID-19								
Normal	11	(8.9)	11	15.55	11	(8.7)	12	16.53
Mild impairment	10	(8.3)	10	14.33	9	(7.5)	10	14.24
Moderate impairment	5	(10.6)	5	18.64	3	(6.8)	3	12.51
COVID-19 pneumonia								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Cystitis								
Normal	2	(1.6)	2	2.83	2	(1.6)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Diabetic foot infection								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Eye infection								
Normal	0				0			
Mild impairment	0				2	(1.7)	2	2.85
Moderate impairment	0				0			
Fungal infection								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fungal skin infection								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Gastroenteritis								
Normal	3	(2.4)	3	4.24	3	(2.4)	3	4.13
Mild impairment	2	(1.7)	2	2.87	1	(0.8)	2	2.85
Moderate impairment	2	(4.3)	2	7.45	1	(2.3)	1	4.17
Gastroenteritis viral								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Gingivitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Herpes zoster								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				1	(2.3)	1	4.17
Infected dermal cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Influenza								
Normal	3	(2.4)	3	4.24	4	(3.1)	6	8.27
Mild impairment	1	(0.8)	1	1.43	3	(2.5)	3	4.27
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Laryngitis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Localised infection								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Nasopharyngitis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	4	(3.3)	4	5.73	8	(6.7)	9	12.81
Moderate impairment	4	(8.5)	4	14.91	3	(6.8)	5	20.84
Oral herpes								
Normal	1	(0.8)	2	2.83	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Osteomyelitis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Otitis media								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Otitis media acute								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Paronychia								
Normal	0				0			
Mild impairment	0				1	(0.8)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Periodontitis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Pharyngitis								
Normal	3	(2.4)	3	4.24	4	(3.1)	4	5.51
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Pharyngotonsillitis								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Pneumonia								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				1	(2.3)	1	4.17
Pneumonia viral								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Post procedural infection								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Pulmonary tuberculoma								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulpitis dental								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Respiratory syncytial virus infection								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Respiratory tract infection								
Normal	1	(0.8)	1	1.41	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Respiratory tract infection viral								
Normal	4	(3.3)	5	7.07	4	(3.1)	5	6.89
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				1	(2.3)	1	4.17
Sepsis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Sinusitis								
Normal	2	(1.6)	3	4.24	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Soft tissue infection								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth abscess								
Normal	0				0			
Mild impairment	2	(1.7)	2	2.87	1	(0.8)	2	2.85
Moderate impairment	0				1	(2.3)	1	4.17
Tooth infection								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Upper respiratory tract infection								
Normal	4	(3.3)	4	5.65	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	3	(2.5)	3	4.27
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Urinary tract infection								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	4	5.70
Moderate impairment	1	(2.1)	1	3.73	2	(4.5)	2	8.34

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral infection								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Viral rhinitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Viral tracheitis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vulvovaginal mycotic infection								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	7	(5.7)	9	12.72	11	(8.7)	14	19.29
Mild impairment	8	(6.6)	10	14.33	12	(10.0)	15	21.36
Moderate impairment	4	(8.5)	6	22.36	4	(9.1)	6	25.01
Accidental overdose								
Normal	1	(0.8)	1	1.41	2	(1.6)	3	4.13
Mild impairment	0				0			
Moderate impairment	0				0			
Accidental underdose								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Animal bite								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Arthropod bite								
Normal	0				1	(0.8)	1	1.38
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Chillblains								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Concussion								
Normal	0				2	(1.6)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
Contusion								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Crush injury								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Exposure to SARS-CoV-2								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Extra dose administered								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fall								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Foot fracture								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Incorrect dose administered								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	0				1	(0.8)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Joint injury								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Ligament sprain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Limb injury								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				2	(1.7)	2	2.85
Moderate impairment	0				0			
Medication error								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Meniscus injury								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Muscle injury								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Muscle strain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Overdose								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Product administration error								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Skin abrasion								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Skin laceration								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Spinal column injury								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Spinal compression fracture								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Subcutaneous haematoma								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Subdural haematoma								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Thermal burn								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Tooth fracture								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Vaccination complication								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				2	(1.7)	2	2.85
Moderate impairment	0				1	(2.3)	1	4.17
Wound								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Wrong product administered								
Normal	1	(0.8)	2	2.83	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Investigations								
All								
Normal	7	(5.7)	9	12.72	5	(3.9)	6	8.27
Mild impairment	3	(2.5)	3	4.30	6	(5.0)	6	8.54
Moderate impairment	2	(4.3)	3	11.18	2	(4.5)	2	8.34
Amylase increased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Blood alkaline phosphatase increased								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood creatinine increased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Blood pressure increased								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Blood triglycerides increased								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood urine present								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Catheterisation cardiac								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Electrocardiogram abnormal								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Electrocardiogram T wave inversion								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Eosinophil count increased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Glomerular filtration rate decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Haematocrit increased								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Haemoglobin increased								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Liver function test abnormal								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Liver function test increased								
Normal	1	(0.8)	1	1.41	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Platelet count decreased								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
SARS-CoV-2 test positive								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Transaminases increased								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Weight increased								
Normal	4	(3.3)	4	5.65	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Metabolism and nutrition disorders								
All								
Normal	7	(5.7)	9	12.72	8	(6.3)	9	12.40
Mild impairment	6	(5.0)	7	10.03	6	(5.0)	7	9.97
Moderate impairment	2	(4.3)	2	7.45	6	(13.6)	6	25.01
Decreased appetite								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Dehydration								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Dyslipidaemia								
Normal	2	(1.6)	3	4.24	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				0			
Fluid retention								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Hypercholesterolaemia								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperglycaemia								
Normal	0				2	(1.6)	2	2.76
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				2	(4.5)	2	8.34
Hyperkalaemia								
Normal	0				2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Hypertriglyceridaemia								
Normal	1	(0.8)	1	1.41	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Hypoalbuminaemia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Hypoglycaemia								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Hypokalaemia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Hyponatraemia								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Increased appetite								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Lipomatosis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Vitamin D deficiency								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Musculoskeletal and connective tissue disorders								
All								
Normal	12	(9.8)	16	22.62	16	(12.6)	23	31.69

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	17	(14.0)	21	30.09	17	(14.2)	23	32.75
Moderate impairment	3	(6.4)	4	14.91	2	(4.5)	2	8.34
Arthralgia								
Normal	1	(0.8)	1	1.41	4	(3.1)	4	5.51
Mild impairment	4	(3.3)	5	7.16	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Arthritis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Back disorder								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Back pain								
Normal	4	(3.3)	4	5.65	4	(3.1)	4	5.51
Mild impairment	3	(2.5)	3	4.30	7	(5.8)	7	9.97
Moderate impairment	1	(2.1)	1	3.73	0			
Bone cyst								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Bone pain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Coccydynia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Flank pain								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Foot deformity								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Intervertebral disc protrusion								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Jaw disorder								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Muscle spasms								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Myalgia								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Myositis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Neck pain								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	2	(1.7)	2	2.87	1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Osteoarthritis								
Normal	3	(2.4)	3	4.24	4	(3.1)	5	6.89
Mild impairment	2	(1.7)	2	2.87	3	(2.5)	3	4.27
Moderate impairment	0				0			
Osteochondrosis								
Normal	1	(0.8)	1	1.41	2	(1.6)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
Pain in extremity								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	2	2.85
Moderate impairment	0				0			
Periarthritis								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Periostitis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Rotator cuff syndrome								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Spinal osteoarthritis								
Normal	0				0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendon disorder								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Tendonitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Tenosynovitis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Torticollis								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Trigger finger								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	2	(1.7)	2	2.87	0			
Moderate impairment	1	(2.1)	1	3.73	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	2	(1.6)	2	2.83	2	(1.6)	4	5.51
Mild impairment	2	(1.7)	2	2.87	1	(0.8)	1	1.42
Moderate impairment	0				0			
Adrenal adenoma								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Eye naevus								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Lung adenocarcinoma								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Osteoma								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pancreatic neoplasm								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Small cell lung cancer								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Small intestine neuroendocrine tumour								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Uterine cancer								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Uterine leiomyoma								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 4" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nervous system disorders								
All								
Normal	6	(4.9)	11	15.55	7	(5.5)	14	19.29
Mild impairment	9	(7.4)	15	21.49	15	(12.5)	22	31.33
Moderate impairment	4	(8.5)	6	22.36	7	(15.9)	11	45.85
Anosmia								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Basilar migraine								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Carpal tunnel syndrome								
Normal	2	(1.6)	2	2.83	2	(1.6)	2	2.76
Mild impairment	0				2	(1.7)	2	2.85
Moderate impairment	0				0			
Cerebral arteriosclerosis								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Cerebrovascular accident								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Cerebrovascular disorder								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Cognitive disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Diabetic neuropathy								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Dizziness								
Normal	1	(0.8)	4	5.65	1	(0.8)	2	2.76
Mild impairment	3	(2.5)	4	5.73	1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Dizziness postural								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dysgeusia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Essential tremor								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Facial nerve disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Headache								
Normal	3	(2.4)	3	4.24	2	(1.6)	3	4.13
Mild impairment	4	(3.3)	5	7.16	6	(5.0)	7	9.97
Moderate impairment	1	(2.1)	2	7.45	1	(2.3)	2	8.34
Hemiparesis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoaesthesia								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemic coma								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Hyporeflexia								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Memory impairment								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Migraine								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Morton's neuralgia								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neuropathy peripheral								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Paraesthesia								
Normal	0				0			
Mild impairment	0				2	(1.7)	2	2.85
Moderate impairment	0				1	(2.3)	1	4.17
Sciatica								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Sleep deficit								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Transient ischaemic attack								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Tremor								
Normal	0				0			
Mild impairment	0				1	(0.8)	4	5.70
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	2	8.34
Vascular encephalopathy								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Normal	1	(0.8)	1	1.41	5	(3.9)	5	6.89
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				2	(4.5)	2	8.34
Affect lability								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Depression								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				1	(2.3)	1	4.17
Fear								
Normal	0				2	(1.6)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
Insomnia								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Mental status changes								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Mixed anxiety and depressive disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Phobia								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Sleep disorder								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Normal	1	(0.8)	2	2.83	1	(0.8)	1	1.38
Mild impairment	2	(1.7)	4	5.73	1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	4	(9.1)	4	16.67
Acute kidney injury								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Chronic kidney disease								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	1	(2.3)	1	4.17
Dysuria								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Haematuria								
Normal	0				0			
Mild impairment	1	(0.8)	2	2.87	0			
Moderate impairment	0				0			
Hydrocalyx								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Nephropathy								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Renal colic								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Renal cyst								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				1	(2.3)	1	4.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	0				0			
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Menopausal disorder								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	8	(6.5)	11	15.55	6	(4.7)	9	12.40
Mild impairment	6	(5.0)	6	8.60	10	(8.3)	11	15.66
Moderate impairment	3	(6.4)	3	11.18	3	(6.8)	3	12.51
Asthma								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Bronchitis chronic								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Cough								
Normal	1	(0.8)	1	1.41	2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	2	(1.7)	2	2.85
Moderate impairment	1	(2.1)	1	3.73	0			
Dyspnoea								
Normal	0				2	(1.6)	3	4.13
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	2	(4.5)	2	8.34
Emphysema								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epistaxis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	2	2.85
Moderate impairment	0				0			
Nasal congestion								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Nasal septum deviation								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Oropharyngeal pain								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Paranasal cyst								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Pleurisy								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pulmonary fibrosis								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pulmonary hypertension								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory disorder								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				1	(2.3)	1	4.17
Rhinitis allergic								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Rhinorrhoea								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus congestion								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Sinus pain								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	2	(1.6)	2	2.83	8	(6.3)	8	11.02
Mild impairment	8	(6.6)	9	12.90	5	(4.2)	6	8.54
Moderate impairment	2	(4.3)	2	7.45	2	(4.5)	2	8.34
Alopecia								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Blister								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	1	(2.1)	1	3.73	0			
Dermatitis contact								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Eczema								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Hyperhidrosis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	1	(2.1)	1	3.73	0			
Hyperkeratosis								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Intertrigo								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Lipohypertrophy								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Pruritus								
Normal	0				2	(1.6)	2	2.76
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				1	(2.3)	1	4.17
Rash								
Normal	0				1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Seborrhoea								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Skin reaction								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Skin ulcer								
Normal	1	(0.8)	1	1.41	1	(0.8)	1	1.38
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			
Umbilical haematoma								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Urticaria								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Normal	2	(1.6)	2	2.83	0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Cardiac pacemaker replacement								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Shoulder operation								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth extraction								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vascular disorders								
All								
Normal	3	(2.4)	6	8.48	7	(5.5)	10	13.78
Mild impairment	4	(3.3)	5	7.16	6	(5.0)	6	8.54
Moderate impairment	1	(2.1)	1	3.73	3	(6.8)	3	12.51
Aortic arteriosclerosis								
Normal	0				2	(1.6)	2	2.76
Mild impairment	0				0			
Moderate impairment	0				0			
Arteriosclerosis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Blood pressure fluctuation								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Deep vein thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(2.1)	1	3.73	0			
Diabetic vascular disorder								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	1	(0.8)	1	1.42
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haematoma								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Hypertension								
Normal	0				1	(0.8)	1	1.38
Mild impairment	2	(1.7)	2	2.87	4	(3.3)	4	5.70
Moderate impairment	0				1	(2.3)	1	4.17
Hypertensive crisis								
Normal	1	(0.8)	1	1.41	1	(0.8)	3	4.13
Mild impairment	0				0			
Moderate impairment	0				0			
Hypertensive urgency								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			
Hypotension								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(2.3)	1	4.17
Neovascularisation								
Normal	0				0			
Mild impairment	0				1	(0.8)	1	1.42
Moderate impairment	0				0			
Orthostatic hypotension								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Peripheral arterial occlusive disease								
Normal	1	(0.8)	1	1.41	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Peripheral artery stenosis								
Normal	1	(0.8)	3	4.24	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Peripheral venous disease								
Normal	0				0			
Mild impairment	1	(0.8)	1	1.43	0			
Moderate impairment	0				0			
Thrombophlebitis								
Normal	0				1	(0.8)	1	1.38
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.48 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	197				190			
Mild impairment	88				93			
Moderate impairment	5				9			
PYE (years)								
Normal	97.36				93.48			
Mild impairment	42.42				46.13			
Moderate impairment	2.54				4.51			
Events								
Normal	124	(62.9)	319	327.67	118	(62.1)	325	347.65
Mild impairment	62	(70.5)	182	429.07	65	(69.9)	281	609.18
Moderate impairment	3	(60.0)	6	236.66	7	(77.8)	13	288.30
Blood and lymphatic system disorders								
All								
Normal	1	(0.5)	1	1.03	3	(1.6)	3	3.21
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Anaemia								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Iron deficiency anaemia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Lymphadenitis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Lymphadenopathy								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Thrombocytopenia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Normal	4	(2.0)	4	4.11	3	(1.6)	4	4.28
Mild impairment	5	(5.7)	5	11.79	2	(2.2)	2	4.34
Moderate impairment	0				0			
Angina pectoris								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Angina unstable								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Atrial fibrillation								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Bundle branch block right								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiac failure								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Cardiomegaly								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Cardiovascular disorder								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Myocardial ischaemia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Palpitations								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ventricular extrasystoles								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Ear and labyrinth disorders								
All								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Deafness neurosensory								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Ear pain								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Vertigo								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Endocrine disorders								
All								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hypothyroidism								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Eye disorders								
All								
Normal	11	(5.6)	15	15.41	15	(7.9)	20	21.39
Mild impairment	18	(20.5)	22	51.87	12	(12.9)	16	34.69
Moderate impairment	0				1	(11.1)	1	22.18
Arteriosclerotic retinopathy								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Astigmatism								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Cataract								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	3	(3.4)	3	7.07	1	(1.1)	1	2.17
Moderate impairment	0				0			
Cataract nuclear								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Conjunctival haemorrhage								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Corneal erosion								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Diabetic retinal oedema								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				1	(11.1)	1	22.18
Diabetic retinopathy								
Normal	6	(3.0)	6	6.16	9	(4.7)	9	9.63
Mild impairment	6	(6.8)	6	14.15	5	(5.4)	5	10.84
Moderate impairment	0				0			
Dry eye								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Epiretinal membrane								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Glaucoma								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	3	(3.2)	3	6.50
Moderate impairment	0				0			
Macular oedema								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	2	(2.3)	3	7.07	0			
Moderate impairment	0				0			
Myopia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Non-proliferative retinopathy								
Normal	0				1	(0.5)	1	1.07
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	1	2.17
Moderate impairment	0				0			
Ocular hypertension								
Normal	0				0			
Mild impairment	0				1	(1.1)	2	4.34
Moderate impairment	0				0			
Photopsia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Presbyopia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Pterygium								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Retinal vascular disorder								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Retinopathy								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Retinopathy hypertensive								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
Normal	0				0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Vitreous detachment								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Vitreous floaters								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Gastrointestinal disorders								
All								
Normal	17	(8.6)	25	25.68	12	(6.3)	21	22.46
Mild impairment	9	(10.2)	13	30.65	12	(12.9)	20	43.36
Moderate impairment	0				0			
Abdominal discomfort								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Abdominal distension								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Abdominal pain								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Abdominal pain upper								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Anal fissure								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Chronic gastritis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	2	(2.2)	2	4.34
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Constipation								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dental caries								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Diarrhoea								
Normal	4	(2.0)	5	5.14	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	3	(3.2)	4	8.67
Moderate impairment	0				0			
Diverticulum intestinal								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Dyspepsia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Faeces soft								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Gastric polyps								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Gastritis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Gastritis erosive								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Gastrooesophageal reflux disease								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Gingival recession								
Normal	0				1	(0.5)	2	2.14

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Haemorrhoids								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Hiatus hernia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Impaired gastric emptying								
Normal	0				0			
Mild impairment	1	(1.1)	2	4.72	0			
Moderate impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Lumbar hernia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Nausea								
Normal	3	(1.5)	3	3.08	4	(2.1)	4	4.28
Mild impairment	1	(1.1)	1	2.36	4	(4.3)	4	8.67
Moderate impairment	0				0			
Odynophagia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Pancreatic failure								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pneumatosis intestinalis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Toothache								
Normal	1	(0.5)	1	1.03	3	(1.6)	5	5.35
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vomiting								
Normal	6	(3.0)	6	6.16	4	(2.1)	4	4.28
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
General disorders and administration site conditions								
All								
Normal	22	(11.2)	27	27.73	18	(9.5)	21	22.46
Mild impairment	18	(20.5)	22	51.87	15	(16.1)	61	132.24
Moderate impairment	1	(20.0)	1	39.44	1	(11.1)	1	22.18
Asthenia								
Normal	0				2	(1.1)	2	2.14
Mild impairment	0				0			
Moderate impairment	0				0			
Chest pain								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	22.18
Fatigue								
Normal	3	(1.5)	3	3.08	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	2	4.72	0			
Moderate impairment	1	(20.0)	1	39.44	0			
Hunger								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	2	4.34
Moderate impairment	0				0			
Hyperthermia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Inflammation								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Influenza like illness								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Injection site mass								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injection site pain								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Injection site urticaria								
Normal	1	(0.5)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Malaise								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	3	(3.2)	44	95.39
Moderate impairment	0				0			
Medical device site bruise								
Normal	0				0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Medical device site dermatitis								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	2	(2.3)	2	4.72	2	(2.2)	3	6.50
Moderate impairment	0				0			
Medical device site erythema								
Normal	0				2	(1.1)	3	3.21
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Medical device site haematoma								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Medical device site haemorrhage								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Medical device site irritation								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Medical device site pain								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Medical device site pruritus								
Normal	1	(0.5)	1	1.03	2	(1.1)	2	2.14

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Medical device site rash								
Normal	2	(1.0)	2	2.05	3	(1.6)	3	3.21
Mild impairment	4	(4.5)	4	9.43	4	(4.3)	4	8.67
Moderate impairment	0				0			
Medical device site reaction								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Oedema peripheral								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Pain								
Normal	3	(1.5)	3	3.08	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pyrexia								
Normal	5	(2.5)	6	6.16	2	(1.1)	2	2.14
Mild impairment	4	(4.5)	4	9.43	4	(4.3)	4	8.67
Moderate impairment	0				0			
Swelling face								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site pain								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
Normal	3	(1.5)	3	3.08	1	(0.5)	1	1.07
Mild impairment	2	(2.3)	3	7.07	3	(3.2)	3	6.50
Moderate impairment	0				0			
Gallbladder disorder								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Gallbladder polyp								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Hepatic calcification								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Hepatic steatosis								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Hypertransaminasaemia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Immune system disorders								
All								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hypersensitivity								
Normal	2	(1.0)	2	2.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Seasonal allergy								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Infections and infestations								
All								
Normal	72	(36.5)	107	109.91	70	(36.8)	99	105.90
Mild impairment	31	(35.2)	39	91.94	27	(29.0)	43	93.22
Moderate impairment	1	(20.0)	1	39.44	4	(44.4)	6	133.06
Abscess limb								
Normal	0				1	(0.5)	2	2.14
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Acute sinusitis								
Normal	0				2	(1.1)	2	2.14
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Breast abscess								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Bronchitis								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	1	2.17
Moderate impairment	0				0			
Conjunctivitis								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Coronavirus infection								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
COVID-19								
Normal	22	(11.2)	23	23.62	28	(14.7)	30	32.09
Mild impairment	7	(8.0)	7	16.50	3	(3.2)	3	6.50
Moderate impairment	0				1	(11.1)	1	22.18

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Cystitis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	1	2.17
Moderate impairment	0				0			
Cystitis escherichia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Eye infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fungal skin infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Gastric infection								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Gastroenteritis								
Normal	2	(1.0)	3	3.08	1	(0.5)	1	1.07
Mild impairment	4	(4.5)	4	9.43	1	(1.1)	1	2.17
Moderate impairment	0				0			
Gastroenteritis viral								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Gastrointestinal infection								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	2	4.34
Moderate impairment	0				0			
Genital infection fungal								
Normal	1	(0.5)	2	2.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Gingivitis								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Herpes zoster								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Hordeolum								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Infected cyst								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Influenza								
Normal	1	(0.5)	1	1.03	3	(1.6)	3	3.21
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Laryngitis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Localised infection								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Lower respiratory tract infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Nasopharyngitis								
Normal	25	(12.7)	32	32.87	26	(13.7)	31	33.16
Mild impairment	8	(9.1)	9	21.22	8	(8.6)	10	21.68
Moderate impairment	1	(20.0)	1	39.44	2	(22.2)	2	44.35

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Norovirus infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				1	(11.1)	1	22.18
Otitis media								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Periodontitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Pharyngitis								
Normal	3	(1.5)	3	3.08	0			
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	1	2.17
Moderate impairment	0				0			
Pneumonia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory tract infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory tract infection viral								
Normal	3	(1.5)	3	3.08	2	(1.1)	2	2.14
Mild impairment	0				0			
Moderate impairment	0				0			
Rhinitis								
Normal	0				2	(1.1)	2	2.14
Mild impairment	2	(2.3)	2	4.72	2	(2.2)	3	6.50
Moderate impairment	0				0			
Severe acute respiratory syndrome								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Sinusitis								
Normal	4	(2.0)	4	4.11	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Skin infection								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Tinea cruris								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tinea pedis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Tonsillitis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth abscess								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth infection								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Upper respiratory tract infection								
Normal	4	(2.0)	4	4.11	5	(2.6)	6	6.42
Mild impairment	2	(2.3)	2	4.72	2	(2.2)	2	4.34
Moderate impairment	0				0			
Urinary tract infection								
Normal	3	(1.5)	3	3.08	3	(1.6)	3	3.21
Mild impairment	3	(3.4)	3	7.07	2	(2.2)	3	6.50
Moderate impairment	0				1	(11.1)	2	44.35

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaginal infection								
Normal	1	(0.5)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Viral infection								
Normal	1	(0.5)	1	1.03	3	(1.6)	3	3.21
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Vulvitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Vulvovaginitis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	21	(10.7)	27	27.73	23	(12.1)	29	31.02
Mild impairment	9	(10.2)	10	23.58	9	(9.7)	9	19.51
Moderate impairment	0				1	(11.1)	1	22.18
Accidental overdose								
Normal	4	(2.0)	4	4.11	1	(0.5)	1	1.07
Mild impairment	3	(3.4)	4	9.43	0			
Moderate impairment	0				0			
Anaemia postoperative								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Animal scratch								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Arthropod bite								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Back injury								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Burns first degree								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Clavicle fracture								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Contusion								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				1	(11.1)	1	22.18
Corneal abrasion								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Epicondylitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Face injury								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Fall								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Fibula fracture								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hand fracture								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Heat stroke								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Incorrect dose administered								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Joint injury								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Ligament sprain								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Limb injury								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Medication error								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Muscle strain								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Nerve injury								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Prescribed overdose								
Normal	3	(1.5)	3	3.08	0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Procedural pain								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Product administration error								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Product dispensing error								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Road traffic accident								
Normal	1	(0.5)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin abrasion								
Normal	1	(0.5)	2	2.05	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Skin laceration								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth fracture								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination complication								
Normal	5	(2.5)	5	5.14	7	(3.7)	10	10.70
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Wound								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Wound dehiscence								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Wrong product administered								
Normal	0				4	(2.1)	4	4.28
Mild impairment	0				0			
Moderate impairment	0				0			
Investigations								
All								
Normal	9	(4.6)	9	9.24	11	(5.8)	13	13.91
Mild impairment	5	(5.7)	6	14.15	2	(2.2)	2	4.34
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angiogram								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Aspartate aminotransferase increased								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood cholesterol increased								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Blood glucose increased								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Blood pressure increased								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood testosterone decreased								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood triglycerides increased								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood uric acid increased								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Cardiac murmur								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Electrocardiogram abnormal								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Eosinophil count increased								
Normal	0				1	(0.5)	2	2.14

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Haemoglobin decreased								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Heart rate increased								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatic enzyme increased								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatitis B virus test positive								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Lipids abnormal								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Low density lipoprotein increased								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Mycobacterium tuberculosis complex test positive								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Occult blood positive								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
SARS-CoV-2 test positive								
Normal	0				4	(2.1)	4	4.28
Mild impairment	0				0			
Moderate impairment	0				0			
Weight decreased								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Weight increased								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
White blood cell count decreased								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Normal	6	(3.0)	6	6.16	6	(3.2)	6	6.42
Mild impairment	2	(2.3)	4	9.43	3	(3.2)	5	10.84
Moderate impairment	0				0			
Dehydration								
Normal	0				0			
Mild impairment	0				1	(1.1)	2	4.34
Moderate impairment	0				0			
Hypercholesterolaemia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperuricaemia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemia								
Normal	3	(1.5)	3	3.08	2	(1.1)	2	2.14
Mild impairment	2	(2.3)	4	9.43	1	(1.1)	2	4.34
Moderate impairment	0				0			
Hyponatraemia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Insulin resistance								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Obesity								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Vitamin D deficiency								
Normal	1	(0.5)	1	1.03	2	(1.1)	2	2.14
Mild impairment	0				0			
Moderate impairment	0				0			
Musculoskeletal and connective tissue disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	19	(9.6)	22	22.60	20	(10.5)	41	43.86
Mild impairment	8	(9.1)	9	21.22	17	(18.3)	20	43.36
Moderate impairment	0				2	(22.2)	2	44.35
Arthralgia								
Normal	4	(2.0)	4	4.11	5	(2.6)	5	5.35
Mild impairment	2	(2.3)	2	4.72	3	(3.2)	3	6.50
Moderate impairment	0				1	(11.1)	1	22.18
Arthritis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Back pain								
Normal	3	(1.5)	3	3.08	7	(3.7)	21	22.46
Mild impairment	0				3	(3.2)	3	6.50
Moderate impairment	0				1	(11.1)	1	22.18
Bursitis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Chondromalacia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Groin pain								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Limb discomfort								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Limb mass								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Muscle spasms								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscular weakness								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Musculoskeletal stiffness								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Myalgia								
Normal	1	(0.5)	1	1.03	4	(2.1)	4	4.28
Mild impairment	1	(1.1)	1	2.36	3	(3.2)	4	8.67
Moderate impairment	0				0			
Neck pain								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Nodal osteoarthritis								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Osteoarthritis								
Normal	3	(1.5)	3	3.08	1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Pain in extremity								
Normal	3	(1.5)	3	3.08	4	(2.1)	4	4.28
Mild impairment	3	(3.4)	3	7.07	2	(2.2)	2	4.34
Moderate impairment	0				0			
Periarthritis								
Normal	0				2	(1.1)	2	2.14
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Rheumatoid arthritis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Synovial cyst								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendonitis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Tenosynovitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Trigger finger								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	2	4.34
Moderate impairment	0				0			
Benign neoplasm of thyroid gland								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Benign renal neoplasm								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Eye naevus								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Melanocytic naevus								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Uterine leiomyoma								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Nervous system disorders								
All								
Normal	18	(9.1)	27	27.73	8	(4.2)	11	11.77
Mild impairment	7	(8.0)	17	40.08	16	(17.2)	67	145.25
Moderate impairment	2	(40.0)	2	78.89	0			
Autonomic nervous system imbalance								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Burning sensation								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	39.44	0			
Carpal tunnel syndrome								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Cervicobrachial syndrome								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Diabetic neuropathy								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Disturbance in attention								
Normal	0				0			
Mild impairment	1	(1.1)	9	21.22	0			
Moderate impairment	0				0			
Dizziness								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	1	(1.1)	2	4.72	2	(2.2)	3	6.50
Moderate impairment	0				0			
Dizziness postural								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Encephalopathy								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Haemorrhage intracranial								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Headache								
Normal	11	(5.6)	17	17.46	4	(2.1)	6	6.42
Mild impairment	2	(2.3)	2	4.72	6	(6.5)	7	15.18
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoaesthesia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Hypoglycaemic seizure								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemic unconsciousness								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hypotonia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Loss of consciousness								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Migraine								
Normal	1	(0.5)	2	2.05	1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Neuropathy peripheral								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Sinus headache								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Somnolence								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	39.44	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Speech disorder								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Syncope								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tremor								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	48	104.06
Moderate impairment	0				0			
Psychiatric disorders								
All								
Normal	5	(2.5)	5	5.14	6	(3.2)	7	7.49
Mild impairment	0				0			
Moderate impairment	0				0			
Anxiety								
Normal	1	(0.5)	1	1.03	4	(2.1)	4	4.28
Mild impairment	0				0			
Moderate impairment	0				0			
Attention deficit hyperactivity disorder								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Depressed mood								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Depression								
Normal	0				3	(1.6)	3	3.21
Mild impairment	0				0			
Moderate impairment	0				0			
Insomnia								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Sleep disorder								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	3	(3.2)	6	13.01
Moderate impairment	0				0			
Chronic kidney disease								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Diabetic nephropathy								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	4.34
Moderate impairment	0				0			
Hydrocalyx								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Hypertensive nephropathy								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Microalbuminuria								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Renal cyst								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Renal pain								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	2	(1.0)	2	2.05	4	(2.1)	6	6.42
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Dysmenorrhoea								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Ectropion of cervix								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Fibrocystic breast disease								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Ovarian disorder								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Penile pain								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Premenstrual syndrome								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Prostatomegaly								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Respiratory, thoracic and mediastinal disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	13	(6.6)	14	14.38	17	(8.9)	24	25.67
Mild impairment	7	(8.0)	11	25.93	3	(3.2)	4	8.67
Moderate impairment	1	(20.0)	1	39.44	1	(11.1)	1	22.18
Allergic cough								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Bronchial hyperreactivity								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cough								
Normal	0				8	(4.2)	9	9.63
Mild impairment	3	(3.4)	5	11.79	0			
Moderate impairment	0				0			
Dyspnoea exertional								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Epistaxis								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Hiccups								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Nasal congestion								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Oropharyngeal pain								
Normal	5	(2.5)	5	5.14	3	(1.6)	3	3.21
Mild impairment	0				0			
Moderate impairment	0				0			
Pleurisy								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	22.18

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Productive cough								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Pulmonary congestion								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Respiratory disorder								
Normal	4	(2.0)	4	4.11	2	(1.1)	2	2.14
Mild impairment	0				0			
Moderate impairment	0				0			
Rhinitis allergic								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Rhinorrhoea								
Normal	2	(1.0)	2	2.05	5	(2.6)	5	5.35
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Sinus congestion								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	1	(20.0)	1	39.44	0			
Sneezing								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Throat irritation								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Upper-airway cough syndrome								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	16	(8.1)	16	16.43	12	(6.3)	14	14.98
Mild impairment	7	(8.0)	7	16.50	11	(11.8)	17	36.85
Moderate impairment	1	(20.0)	1	39.44	1	(11.1)	1	22.18

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alopecia								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Angioedema								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Blister								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Chronic spontaneous urticaria								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	0				4	(4.3)	8	17.34
Moderate impairment	0				1	(11.1)	1	22.18
Dermal cyst								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Dermatitis								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	2	(2.3)	2	4.72	1	(1.1)	1	2.17
Moderate impairment	0				0			
Dermatitis atopic								
Normal	0				2	(1.1)	2	2.14
Mild impairment	0				0			
Moderate impairment	0				0			
Dermatitis contact								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	0				5	(5.4)	5	10.84
Moderate impairment	0				0			
Dry skin								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	1	(1.1)	1	2.17
Moderate impairment	0				0			
Eczema								
Normal	0				1	(0.5)	1	1.07

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Erythema								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Hidradenitis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperkeratosis								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Ingrown hair								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Lichen sclerosus								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Macule								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pruritus								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Rash								
Normal	2	(1.0)	2	2.05	0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Rash erythematous								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin irritation								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	39.44	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

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adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin lesion								
Normal	0				1	(0.5)	1	1.07
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Telangiectasia								
Normal	0				1	(0.5)	1	1.07
Mild impairment	0				0			
Moderate impairment	0				0			
Urticaria								
Normal	0				2	(1.1)	2	2.14
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			
Xeroderma								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Surgical and medical procedures								
All								
Normal	0				0			
Mild impairment	2	(2.3)	2	4.72	0			
Moderate impairment	0				0			
Cardiac ablation								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			
Skin neoplasm excision								
Normal	0				0			
Mild impairment	1	(1.1)	1	2.36	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
Normal	2	(1.0)	2	2.05	1	(0.5)	1	1.07
Mild impairment	4	(4.5)	4	9.43	3	(3.2)	3	6.50
Moderate impairment	0				0			
Arteriosclerosis								
Normal	1	(0.5)	1	1.03	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypertension								
Normal	1	(0.5)	1	1.03	1	(0.5)	1	1.07
Mild impairment	4	(4.5)	4	9.43	2	(2.2)	2	4.34
Moderate impairment	0				0			
Varicose vein								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	2.17
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.49 Adverse events by baseline hepatic function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	470				458			
Impaired	1				1			
Missing	21				33			
PYE (years)								
Normal	464.91				450.98			
Impaired	0.31				1.00			
Missing	20.66				33.06			
Events								
Normal	336	(71.5)	1175	252.74	308	(67.2)	1037	229.94
Impaired	0				1	(100.0)	4	400.27
Missing	15	(71.4)	52	251.73	26	(78.8)	121	366.04
Serious								
Yes								
Normal	50	(10.6)	72	15.49	46	(10.0)	69	15.30
Impaired	0				1	(100.0)	2	200.14
Missing	1	(4.8)	2	9.68	2	(6.1)	2	6.05
No								
Normal	323	(68.7)	1103	237.25	301	(65.7)	968	214.64
Impaired	0				1	(100.0)	2	200.14
Missing	15	(71.4)	50	242.05	26	(78.8)	119	359.99
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	17	(3.6)	25	5.38	20	(4.4)	34	7.54
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Moderate								
Normal	146	(31.1)	272	58.51	126	(27.5)	238	52.77
Impaired	0				1	(100.0)	1	100.07
Missing	6	(28.6)	8	38.73	9	(27.3)	12	36.30
Mild								
Normal	280	(59.6)	878	188.85	261	(57.0)	765	169.63
Impaired	0				1	(100.0)	3	300.21
Missing	12	(57.1)	43	208.16	24	(72.7)	109	329.74
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	19	(4.0)	27	5.81	25	(5.5)	39	8.65
Impaired	0				1	(100.0)	1	100.07
Missing	0				3	(9.1)	5	15.13
Possible								
Normal	33	(7.0)	45	9.68	27	(5.9)	41	9.09
Impaired	0				0			
Missing	1	(4.8)	1	4.84	4	(12.1)	5	15.13
Unlikely								
Normal	328	(69.8)	1102	237.03	298	(65.1)	956	211.98
Impaired	0				1	(100.0)	3	300.21
Missing	15	(71.4)	51	246.89	26	(78.8)	111	335.79
Missing								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
No								
Normal	335	(71.3)	1174	252.52	308	(67.2)	1036	229.72
Impaired	0				1	(100.0)	4	400.27
Missing	15	(71.4)	52	251.73	26	(78.8)	121	366.04
NA								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	4	(0.9)	5	1.08	2	(0.4)	3	0.67
Impaired	0				0			
Missing	0				0			
Not recovered/not resolved								
Normal	151	(32.1)	314	67.54	141	(30.8)	255	56.54
Impaired	0				1	(100.0)	3	300.21
Missing	6	(28.6)	10	48.41	17	(51.5)	32	96.80
Recovered/resolved with sequelae								
Normal	6	(1.3)	6	1.29	5	(1.1)	6	1.33
Impaired	0				0			
Missing	0				0			
Recovering/resolving								
Normal	19	(4.0)	26	5.59	16	(3.5)	17	3.77
Impaired	0				1	(100.0)	1	100.07
Missing	0				3	(9.1)	3	9.08
Recovered/resolved								
Normal	295	(62.8)	824	177.24	272	(59.4)	756	167.64
Impaired	0				0			
Missing	13	(61.9)	42	203.32	21	(63.6)	86	260.16
Unknown								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.50 Adverse events by baseline hepatic function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	251				246			
Impaired	0				0			
Missing	11				17			
PYE (years)								
Normal	148.85				143.85			
Impaired	0				0			
Missing	6.39				8.92			
Events								
Normal	153	(61.0)	427	286.86	128	(52.0)	317	220.36
Impaired	0				0			
Missing	8	(72.7)	39	610.05	6	(35.3)	11	123.36
Serious								
Yes								
Normal	21	(8.4)	28	18.81	14	(5.7)	18	12.51
Impaired	0				0			
Missing	1	(9.1)	2	31.28	2	(11.8)	2	22.43
No								
Normal	150	(59.8)	399	268.05	124	(50.4)	299	207.85
Impaired	0				0			
Missing	8	(72.7)	37	578.77	4	(23.5)	9	100.93
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	10	(4.0)	15	10.08	9	(3.7)	11	7.65
Impaired	0				0			
Missing	1	(9.1)	2	31.28	2	(11.8)	2	22.43
Moderate								
Normal	61	(24.3)	116	77.93	54	(22.0)	82	57.00
Impaired	0				0			
Missing	3	(27.3)	6	93.85	0			
Mild								
Normal	125	(49.8)	296	198.85	105	(42.7)	224	155.71
Impaired	0				0			
Missing	7	(63.6)	31	484.91	4	(23.5)	9	100.93
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	9	(3.6)	9	6.05	5	(2.0)	12	8.34
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Possible								
Normal	15	(6.0)	24	16.12	7	(2.8)	7	4.87
Impaired	0				0			
Missing	1	(9.1)	2	31.28	0			
Unlikely								
Normal	147	(58.6)	384	257.97	124	(50.4)	295	205.07
Impaired	0				0			
Missing	8	(72.7)	37	578.77	6	(35.3)	10	112.14
Missing								
Normal	6	(2.4)	10	6.72	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
No								
Normal	152	(60.6)	415	278.80	125	(50.8)	312	216.89
Impaired	0				0			
Missing	8	(72.7)	39	610.05	6	(35.3)	11	123.36
NA								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Missing								
Normal	6	(2.4)	10	6.72	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	1	(9.1)	2	31.28	1	(5.9)	1	11.21
Not recovered/not resolved								
Normal	52	(20.7)	92	61.81	46	(18.7)	61	42.40
Impaired	0				0			
Missing	3	(27.3)	5	78.21	2	(11.8)	2	22.43
Recovered/resolved with sequelae								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Recovering/resolving								
Normal	19	(7.6)	24	16.12	15	(6.1)	16	11.12
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Recovered/resolved								
Normal	128	(51.0)	310	208.26	96	(39.0)	238	165.44
Impaired	0				0			
Missing	7	(63.6)	32	500.56	4	(23.5)	7	78.50
Unknown								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.51 Adverse events by baseline hepatic function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	273				279			
Impaired	2				2			
Missing	16				10			
PYE (years)								
Normal	156.77				159.72			
Impaired	1.05				1.14			
Missing	9.54				5.94			
Events								
Normal	162	(59.3)	428	273.00	158	(56.6)	522	326.83
Impaired	2	(100.0)	8	764.92	2	(100.0)	5	437.95
Missing	7	(43.8)	19	199.13	7	(70.0)	23	387.13
Serious								
Yes								
Normal	20	(7.3)	33	21.05	24	(8.6)	32	20.04
Impaired	1	(50.0)	1	95.62	0			
Missing	1	(6.3)	1	10.48	1	(10.0)	1	16.83
No								
Normal	155	(56.8)	395	251.95	151	(54.1)	490	306.80
Impaired	2	(100.0)	7	669.31	2	(100.0)	5	437.95
Missing	7	(43.8)	18	188.65	7	(70.0)	22	370.30
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	11	(4.0)	18	11.48	11	(3.9)	13	8.14
Impaired	1	(50.0)	1	95.62	0			
Missing	1	(6.3)	1	10.48	1	(10.0)	1	16.83
Moderate								
Normal	57	(20.9)	97	61.87	57	(20.4)	115	72.00
Impaired	0				1	(50.0)	1	87.59
Missing	2	(12.5)	2	20.96	3	(30.0)	5	84.16
Mild								
Normal	130	(47.6)	313	199.65	140	(50.2)	394	246.69
Impaired	2	(100.0)	7	669.31	2	(100.0)	4	350.36
Missing	6	(37.5)	16	167.69	6	(60.0)	17	286.14
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	9	(3.3)	13	8.29	6	(2.2)	7	4.38
Impaired	0				1	(50.0)	1	87.59
Missing	0				0			
Possible								
Normal	22	(8.1)	33	21.05	15	(5.4)	34	21.29
Impaired	0				0			
Missing	1	(6.3)	1	10.48	2	(20.0)	9	151.49
Unlikely								
Normal	149	(54.6)	382	243.66	154	(55.2)	481	301.16
Impaired	2	(100.0)	8	764.92	2	(100.0)	4	350.36
Missing	6	(37.5)	18	188.65	6	(60.0)	14	235.65
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	5	(1.8)	5	3.19	3	(1.1)	4	2.50
Impaired	0				0			
Missing	0				0			
No								
Normal	161	(59.0)	423	269.81	158	(56.6)	517	323.70
Impaired	2	(100.0)	8	764.92	2	(100.0)	5	437.95
Missing	7	(43.8)	19	199.13	7	(70.0)	23	387.13
NA								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	2	(0.7)	4	2.55	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Not recovered/not resolved								
Normal	74	(27.1)	130	82.92	68	(24.4)	144	90.16
Impaired	1	(50.0)	4	382.46	1	(50.0)	2	175.18
Missing	3	(18.8)	5	52.40	4	(40.0)	6	100.99
Recovered/resolved with sequelae								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Recovering/resolving								
Normal	14	(5.1)	29	18.50	13	(4.7)	19	11.90
Impaired	1	(50.0)	1	95.62	0			
Missing	1	(6.3)	2	20.96	3	(30.0)	3	50.50
Recovered/resolved								
Normal	135	(49.5)	265	169.03	135	(48.4)	356	222.90
Impaired	2	(100.0)	3	286.85	1	(50.0)	3	262.77
Missing	6	(37.5)	12	125.77	6	(60.0)	14	235.65
Unknown								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.52 Adverse events by baseline hepatic function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	281				285			
Impaired	1				0			
Missing	8				7			
PYE (years)								
Normal	137.79				140.61			
Impaired	0.50				0			
Missing	4.02				3.51			
Events								
Normal	181	(64.4)	479	347.63	183	(64.2)	590	419.60
Impaired	0				0			
Missing	8	(100.0)	28	697.14	7	(100.0)	29	826.23
Serious								
Yes								
Normal	11	(3.9)	15	10.89	6	(2.1)	7	4.98
Impaired	0				0			
Missing	0				1	(14.3)	2	56.98
No								
Normal	177	(63.0)	464	336.74	180	(63.2)	583	414.62
Impaired	0				0			
Missing	8	(100.0)	28	697.14	7	(100.0)	27	769.25
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	9	(3.2)	10	7.26	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				1	(14.3)	2	56.98
Moderate								
Normal	47	(16.7)	81	58.78	47	(16.5)	78	55.47
Impaired	0				0			
Missing	4	(50.0)	9	224.08	4	(57.1)	11	313.40
Mild								
Normal	163	(58.0)	388	281.59	163	(57.2)	509	361.99
Impaired	0				0			
Missing	6	(75.0)	19	473.06	7	(100.0)	16	455.85
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	17	(6.0)	20	14.51	7	(2.5)	8	5.69
Impaired	0				0			
Missing	0				0			
Possible								
Normal	22	(7.8)	26	18.87	16	(5.6)	39	27.74
Impaired	0				0			
Missing	0				1	(14.3)	2	56.98
Unlikely								
Normal	170	(60.5)	433	314.25	182	(63.9)	543	386.17
Impaired	0				0			
Missing	8	(100.0)	28	697.14	7	(100.0)	27	769.25
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
No								
Normal	181	(64.4)	479	347.63	183	(64.2)	590	419.60
Impaired	0				0			
Missing	8	(100.0)	28	697.14	7	(100.0)	29	826.23
NA								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Not recovered/not resolved								
Normal	81	(28.8)	128	92.89	79	(27.7)	131	93.17
Impaired	0				0			
Missing	5	(62.5)	6	149.39	4	(57.1)	13	370.38
Recovered/resolved with sequelae								
Normal	0				3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Recovering/resolving								
Normal	6	(2.1)	6	4.35	5	(1.8)	8	5.69
Impaired	0				0			
Missing	0				0			
Recovered/resolved								
Normal	153	(54.4)	344	249.65	154	(54.0)	448	318.61
Impaired	0				0			
Missing	7	(87.5)	22	547.75	7	(100.0)	16	455.85
Unknown								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

7.16.53 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	470				458			
Impaired	1				1			
Missing	21				33			
PYE (years)								
Normal	464.91				450.98			
Impaired	0.31				1.00			
Missing	20.66				33.06			
Events								
Normal	336	(71.5)	1175	252.74	308	(67.2)	1037	229.94
Impaired	0				1	(100.0)	4	400.27
Missing	15	(71.4)	52	251.73	26	(78.8)	121	366.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	11	(2.3)	11	2.37	8	(1.7)	8	1.77
Impaired	0				0			
Missing	0				3	(9.1)	3	9.08
Anaemia								
Normal	6	(1.3)	6	1.29	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Blood loss anaemia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Eosinophilia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hypochromic anaemia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Iron deficiency anaemia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Lymphadenopathy								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Polycythaemia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Thrombocytopenia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	36	(7.7)	62	13.34	28	(6.1)	36	7.98
Impaired	0				0			
Missing	1	(4.8)	1	4.84	2	(6.1)	2	6.05
Acute coronary syndrome								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Acute myocardial infarction								
Normal	2	(0.4)	2	0.43	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				0			
Angina pectoris								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Angina unstable								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Aortic valve calcification								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Aortic valve incompetence								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Arrhythmia								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Atrial fibrillation								
Normal	8	(1.7)	9	1.94	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				0			
Atrial flutter								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Atrial thrombosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrioventricular block complete								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Bradycardia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Bundle branch block right								
Normal	1	(0.2)	1	0.22	2	(0.4)	3	0.67
Impaired	0				0			
Missing	0				0			
Cardiac dysfunction								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Cardiac failure								
Normal	4	(0.9)	4	0.86	0			
Impaired	0				0			
Missing	0				0			
Cardiac failure chronic								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Cardiac failure congestive								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Cardiac ventricular thrombosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Chronic coronary syndrome								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Coronary artery disease								
Normal	5	(1.1)	5	1.08	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Coronary artery occlusion								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diastolic dysfunction								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Left atrial dilatation								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Left ventricular dysfunction								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Left ventricular hypertrophy								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Mitral valve incompetence								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Myocardial infarction								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Myocardial ischaemia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Palpitations								
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Pericardial effusion								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Pericarditis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Sinus arrhythmia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus bradycardia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Sinus tachycardia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Supraventricular extrasystoles								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tachycardia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tricuspid valve incompetence								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Ventricular extrasystoles								
Normal	4	(0.9)	4	0.86	1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Congenital, familial and genetic disorders								
All								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hydrocele								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Type V hyperlipidaemia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	8	(1.7)	8	1.72	9	(2.0)	10	2.22
Impaired	0				0			
Missing	0				0			
Ear inflammation								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Ear pain								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Eustachian tube dysfunction								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Hypoacusis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Presbyacusis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tinnitus								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	4	(0.9)	4	0.86	5	(1.1)	6	1.33
Impaired	0				0			
Missing	0				0			
Vertigo positional								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	2	(0.4)	2	0.43	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Goitre								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Hyperplasia adrenal								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hyperprolactinaemia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Hyperthyroidism								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Thyroid mass								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	24	(5.1)	34	7.31	21	(4.6)	27	5.99
Impaired	0				0			
Missing	1	(4.8)	1	4.84	4	(12.1)	5	15.13
Acquired epiblepharon								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Asthenopia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Astigmatism								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Blepharitis								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Cataract								
Normal	8	(1.7)	10	2.15	4	(0.9)	5	1.11
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Conjunctival erosion								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Conjunctival haemorrhage								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Conjunctivitis allergic								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Diabetic retinopathy								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Diplopia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dry eye								
Normal	1	(0.2)	1	0.22	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Eye discharge								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Eye inflammation								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Eye pain								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Glaucoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Normal tension glaucoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Ocular hypertension								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Optic disc vascular disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Photophobia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Post thrombotic retinopathy								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Posterior capsule opacification								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Retinal aneurysm								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Retinal artery occlusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Retinal detachment								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Retinal tear								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Retinal vein occlusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Scintillating scotoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Uveitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Visual impairment								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vitreous detachment								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vitreous haemorrhage								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorders								
All								
Normal	80	(17.0)	131	28.18	64	(14.0)	99	21.95
Impaired	0				1	(100.0)	1	100.07
Missing	3	(14.3)	5	24.20	9	(27.3)	14	42.35
Abdominal discomfort								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Abdominal distension								
Normal	5	(1.1)	5	1.08	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Abdominal pain								
Normal	5	(1.1)	5	1.08	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Abdominal pain lower								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Abdominal pain upper								
Normal	2	(0.4)	2	0.43	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	2	6.05
Acid peptic disease								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Anal fissure								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Anal pruritus								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Chronic gastritis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Colitis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Colitis ischaemic								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Colitis microscopic								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	4	(0.9)	4	0.86	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Crohn's disease								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dental caries								
Normal	6	(1.3)	8	1.72	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Diarrhoea								
Normal	30	(6.4)	42	9.03	16	(3.5)	17	3.77
Impaired	0				0			
Missing	1	(4.8)	1	4.84	5	(15.2)	5	15.13
Diverticulum								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Diverticulum intestinal								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Dry mouth								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Duodenitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dyspepsia								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Enteritis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Enterocolitis								
Normal	3	(0.6)	4	0.86	0			
Impaired	0				0			
Missing	0				0			
Epigastric discomfort								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Flatulence								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Food poisoning								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Frequent bowel movements								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Gastric disorder								
Normal	0				0			
Impaired	0				1	(100.0)	1	100.07
Missing	0				0			
Gastric polyps								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastrointestinal inflammation								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	6	(1.3)	6	1.29	6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Haematochezia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Haemorrhoids								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hiatus hernia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hyperaesthesia teeth								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Hyperchlorhydria								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Ileus								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Inguinal hernia								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Intra-abdominal haematoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Irritable bowel syndrome								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Large intestine polyp								
Normal	1	(0.2)	1	0.22	2	(0.4)	3	0.67
Impaired	0				0			
Missing	0				0			
Loose tooth								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Melaena								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	14	(3.0)	15	3.23	4	(0.9)	5	1.11
Impaired	0				0			
Missing	1	(4.8)	1	4.84	1	(3.0)	2	6.05
Oral discomfort								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Pancreatitis								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pancreatitis acute								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pancreatitis chronic								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Periodontal disease								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Periodontal inflammation								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Rectal polyp								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Rectal prolapse								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Stomatitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Tooth disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Tooth impacted								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Toothache								
Normal	8	(1.7)	8	1.72	2	(0.4)	2	0.44
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Ulcerative gastritis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Umbilical hernia								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Vomiting								
Normal	4	(0.9)	4	0.86	7	(1.5)	10	2.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
General disorders and administration site conditions								
All								
Normal	71	(15.1)	107	23.02	68	(14.8)	97	21.51
Impaired	0				0			
Missing	4	(19.0)	7	33.89	10	(30.3)	13	39.33
Asthenia								
Normal	4	(0.9)	4	0.86	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Chest discomfort								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Chest pain								
Normal	4	(0.9)	4	0.86	2	(0.4)	2	0.44

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Chills								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Death								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Discomfort								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Drug intolerance								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Early satiety								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Fatigue								
Normal	13	(2.8)	14	3.01	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Feeling abnormal								
Normal	1	(0.2)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Feeling hot								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Gait disturbance								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Hunger								
Normal	5	(1.1)	6	1.29	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Implant site pruritus								
Normal	1	(0.2)	1	0.22	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Inflammation								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Influenza like illness								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Injection site bruising								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Injection site dermatitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Injection site erythema								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Injection site haemorrhage								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Injection site hypersensitivity								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Injection site hypertrophy								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Injection site mass								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Injection site pain								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Injection site reaction								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Injection site urticaria								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	5	(1.1)	6	1.29	7	(1.5)	9	2.00
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Medical device site bruise								
Normal	4	(0.9)	5	1.08	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Medical device site dermatitis								
Normal	2	(0.4)	5	1.08	6	(1.3)	12	2.66
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Medical device site eczema								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Medical device site erythema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Medical device site haematoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Medical device site haemorrhage								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	2	(9.5)	2	9.68	0			
Medical device site hypersensitivity								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Medical device site inflammation								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Medical device site pain								
Normal	0				1	(0.2)	1	0.22

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Medical device site pruritus								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Medical device site reaction								
Normal	1	(0.2)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Non-cardiac chest pain								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Oedema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Oedema peripheral								
Normal	5	(1.1)	5	1.08	5	(1.1)	6	1.33
Impaired	0				0			
Missing	0				0			
Pain								
Normal	3	(0.6)	3	0.65	5	(1.1)	5	1.11
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Peripheral swelling								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Procedural failure								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pyrexia								
Normal	17	(3.6)	18	3.87	16	(3.5)	17	3.77
Impaired	0				0			
Missing	0				5	(15.2)	5	15.13
Swelling								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Thirst								
Normal	1	(0.2)	1	0.22	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Vaccination site erythema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vaccination site pain								
Normal	4	(0.9)	5	1.08	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Vaccination site reaction								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Hepatobiliary disorders								
All								
Normal	9	(1.9)	12	2.58	5	(1.1)	6	1.33
Impaired	0				1	(100.0)	1	100.07
Missing	0				0			
Cholelithiasis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Hepatic cirrhosis								
Normal	0				0			
Impaired	0				1	(100.0)	1	100.07
Missing	0				0			
Hepatic cyst								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hepatic function abnormal								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hepatic steatosis								
Normal	6	(1.3)	6	1.29	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypertransaminasaemia								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Liver disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Nonalcoholic fatty liver disease								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Steatohepatitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Immune system disorders								
All								
Normal	3	(0.6)	4	0.86	4	(0.9)	5	1.11
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Allergy to arthropod bite								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Immunisation reaction								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Infections and infestations								
All								
Normal	160	(34.0)	251	53.99	175	(38.2)	262	58.10
Impaired	0				1	(100.0)	1	100.07

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	9	(42.9)	12	58.09	17	(51.5)	24	72.60
Abscess								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Acarodermatitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Acute sinusitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Anal abscess								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Asymptomatic COVID-19								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Bacterial infection								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Balanitis candida								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Body tinea								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Breast abscess								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Breast cellulitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	8	(1.7)	8	1.72	4	(0.9)	4	0.89
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Candida infection								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Cellulitis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Chlamydial infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Chronic hepatitis C								
Normal	0				0			
Impaired	0				1	(100.0)	1	100.07
Missing	0				0			
Chronic sinusitis								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Chronic tonsillitis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Clostridium difficile infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Conjunctivitis								
Normal	4	(0.9)	4	0.86	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Coronavirus infection								
Normal	2	(0.4)	2	0.43	3	(0.7)	4	0.89
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	43	(9.1)	43	9.25	58	(12.7)	59	13.08
Impaired	0				0			
Missing	6	(28.6)	6	29.05	3	(9.1)	3	9.08
COVID-19 pneumonia								
Normal	4	(0.9)	4	0.86	3	(0.7)	3	0.67
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Cystitis								
Normal	5	(1.1)	6	1.29	8	(1.7)	9	2.00
Impaired	0				0			
Missing	0				0			
Dermatophytosis of nail								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Diverticulitis								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Ear infection								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Empyema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Endophthalmitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Epididymitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Erysipelas								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Escherichia urinary tract infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Eye infection bacterial								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Folliculitis								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Fungal balanitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Fungal infection								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Furuncle								
Normal	1	(0.2)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastroenteritis								
Normal	4	(0.9)	4	0.86	5	(1.1)	5	1.11
Impaired	0				0			
Missing	0				0			
Gastroenteritis norovirus								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastroenteritis viral								
Normal	4	(0.9)	4	0.86	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gastrointestinal infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Genital infection fungal								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Giardiasis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	2	(0.4)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Helicobacter gastritis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Helicobacter infection								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Herpes dermatitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Herpes simplex								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Herpes virus infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Herpes zoster								
Normal	5	(1.1)	5	1.08	6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Hordeolum								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Infected bite								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	0				3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Labyrinthitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Laryngitis								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Laryngopharyngitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Localised infection								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Lower respiratory tract infection								
Normal	5	(1.1)	5	1.08	2	(0.4)	4	0.89
Impaired	0				0			
Missing	0				0			
Lyme disease								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Mastitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Nail infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	29	(6.2)	35	7.53	29	(6.3)	32	7.10
Impaired	0				0			
Missing	1	(4.8)	1	4.84	5	(15.2)	5	15.13
Onychomycosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Oophoritis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Oral herpes								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Oropharyngeal candidiasis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Osteomyelitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Otitis externa								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Otitis media acute								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Otitis media chronic								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Parotitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Peri-implantitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pericoronitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Periodontitis								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Pharyngitis								
Normal	11	(2.3)	13	2.80	9	(2.0)	11	2.44
Impaired	0				0			
Missing	0				0			
Pharyngotonsillitis								
Normal	0				2	(0.4)	3	0.67
Impaired	0				0			
Missing	0				0			
Pneumonia								
Normal	4	(0.9)	4	0.86	1	(0.2)	1	0.22
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Post procedural infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pulpitis dental								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Purulence								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Respiratory syncytial virus infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection								
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Respiratory tract infection viral								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Rhinitis								
Normal	6	(1.3)	6	1.29	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				0			
Rotavirus infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Salpingitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Sepsis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Sinusitis								
Normal	6	(1.3)	7	1.51	6	(1.3)	8	1.77
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Skin bacterial infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Skin infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Subcutaneous abscess								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Tinea infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Tonsillitis								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tracheitis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Upper respiratory tract infection								
Normal	21	(4.5)	28	6.02	10	(2.2)	11	2.44
Impaired	0				0			
Missing	2	(9.5)	2	9.68	3	(9.1)	3	9.08
Urethritis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Urinary tract infection								
Normal	7	(1.5)	7	1.51	14	(3.1)	15	3.33
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				2	(6.1)	2	6.05
Vaginal infection								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Varicella								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Viral infection								
Normal	3	(0.6)	3	0.65	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				0			
Viral pharyngitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Vulvovaginal candidiasis								
Normal	2	(0.4)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Vulvovaginal mycotic infection								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Injury, poisoning and procedural complications								
All								
Normal	58	(12.3)	63	13.55	37	(8.1)	46	10.20
Impaired	0				0			
Missing	2	(9.5)	2	9.68	3	(9.1)	6	18.15
Accidental overdose								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Animal bite								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ankle fracture								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Arthropod sting								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Bone contusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Burn oral cavity								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Burns first degree								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Cervical vertebral fracture								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Chillblains								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	4	(0.9)	5	1.08	4	(0.9)	4	0.89
Impaired	0				0			
Missing	1	(4.8)	1	4.84	1	(3.0)	1	3.03
Deafness traumatic								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Endotracheal intubation complication								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Eye injury								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fall								
Normal	5	(1.1)	5	1.08	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Fibula fracture								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Foot fracture								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Hand fracture								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Heat illness								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				2	(6.1)	3	9.08
Hip fracture								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Injury								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Joint injury								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Limb injury								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Lower limb fracture								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Meniscus injury								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Muscle strain								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Overdose								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Post procedural fistula								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Post procedural haemorrhage								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Post procedural hypothyroidism								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Post procedural stroke								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Post procedural swelling								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Procedural pain								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Radius fracture								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Rib fracture								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Scar								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Skin abrasion								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Skin laceration								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Soft tissue injury								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Thermal burn								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tooth fracture								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Traumatic haematoma								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Underdose								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vaccination complication								
Normal	10	(2.1)	10	2.15	11	(2.4)	17	3.77
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Wound								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Wrist fracture								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
Normal	21	(4.5)	24	5.16	18	(3.9)	18	3.99
Impaired	0				1	(100.0)	1	100.07
Missing	0				2	(6.1)	3	9.08
Alanine aminotransferase increased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Aspartate aminotransferase increased								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Blood cholesterol increased								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Blood creatine increased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Blood creatine phosphokinase increased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Blood glucose increased								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Blood pressure decreased								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Blood pressure increased								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Blood triglycerides increased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Body temperature increased								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Cardiac stress test abnormal								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Electrocardiogram repolarisation abnormality								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Glycosylated haemoglobin increased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Haemoglobin decreased								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Hepatic enzyme increased								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
International normalised ratio abnormal								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
International normalised ratio decreased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
International normalised ratio increased								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Lipids increased								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Red blood cell count decreased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Transferrin saturation decreased								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Weight decreased								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Weight increased								
Normal	5	(1.1)	5	1.08	8	(1.7)	8	1.77
Impaired	0				1	(100.0)	1	100.07
Missing	0				1	(3.0)	1	3.03
Metabolism and nutrition disorders								
All								
Normal	40	(8.5)	46	9.89	43	(9.4)	53	11.75
Impaired	0				0			
Missing	1	(4.8)	1	4.84	3	(9.1)	7	21.18
Appetite disorder								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Decreased appetite								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dehydration								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Diabetes mellitus								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dyslipidaemia								
Normal	10	(2.1)	10	2.15	6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Electrolyte imbalance								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Fluid retention								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Gout								
Normal	1	(0.2)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Hypercholesterolaemia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hyperglycaemia								
Normal	0				6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Hyperkalaemia								
Normal	4	(0.9)	5	1.08	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Hyperlipidaemia								
Normal	4	(0.9)	4	0.86	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Hypertriglyceridaemia								
Normal	5	(1.1)	5	1.08	4	(0.9)	4	0.89
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Hyperuricaemia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	4	(0.9)	5	1.08	7	(1.5)	15	3.33
Impaired	0				0			
Missing	0				2	(6.1)	5	15.13
Hypokalaemia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Increased appetite								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Iron deficiency								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Malnutrition								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Metabolic disorder								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Obesity								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Vitamin D deficiency								
Normal	4	(0.9)	4	0.86	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Zinc deficiency								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	91	(19.4)	146	31.40	83	(18.1)	121	26.83
Impaired	0				0			
Missing	8	(38.1)	10	48.41	9	(27.3)	12	36.30
Arthralgia								
Normal	19	(4.0)	23	4.95	15	(3.3)	16	3.55
Impaired	0				0			
Missing	4	(19.0)	4	19.36	2	(6.1)	3	9.08
Arthritis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Axillary mass								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Back disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Back pain								
Normal	24	(5.1)	25	5.38	22	(4.8)	23	5.10
Impaired	0				0			
Missing	3	(14.3)	4	19.36	2	(6.1)	2	6.05
Bone cyst								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Bursitis								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Chondropathy								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Coccydynia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Costochondritis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Dupuytren's contracture								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Exostosis								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Fibromyalgia								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fistula								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Flank pain								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Groin pain								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Intervertebral disc disorder								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Intervertebral disc protrusion								
Normal	4	(0.9)	5	1.08	3	(0.7)	4	0.89
Impaired	0				0			
Missing	0				0			
Joint effusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Joint swelling								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Limb deformity								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Lumbar spinal stenosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Mastication disorder								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Muscle contracture								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle spasms								
Normal	8	(1.7)	8	1.72	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Muscular weakness								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Musculoskeletal chest pain								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Musculoskeletal pain								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Musculoskeletal stiffness								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Myalgia								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Myositis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Neck pain								
Normal	5	(1.1)	5	1.08	6	(1.3)	6	1.33
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Osteoarthritis								
Normal	12	(2.6)	14	3.01	8	(1.7)	9	2.00
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Osteochondrosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Osteopenia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pain in extremity								
Normal	15	(3.2)	16	3.44	10	(2.2)	13	2.88
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Periarthritis								
Normal	6	(1.3)	6	1.29	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Plantar fasciitis								
Normal	3	(0.6)	4	0.86	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Polyarthritis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Rotator cuff syndrome								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Spinal osteoarthritis								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Spinal pain								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Spinal stenosis								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Synovial cyst								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Tendonitis								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Tenosynovitis								
Normal	1	(0.2)	1	0.22	4	(0.9)	5	1.11
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tenosynovitis stenosans								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Trigger finger								
Normal	1	(0.2)	1	0.22	2	(0.4)	4	0.89
Impaired	0				0			
Missing	0				0			
Vertebral osteophyte								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	9	(1.9)	11	2.37	4	(0.9)	8	1.77
Impaired	0				0			
Missing	2	(9.5)	2	9.68	1	(3.0)	1	3.03
Acrochordon								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Basal cell carcinoma								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Colon cancer								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dysplastic naevus								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Glioblastoma multiforme								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Haemangioma of liver								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatocellular carcinoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Malignant melanoma in situ								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Metastases to liver								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Neoplasm skin								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Oral fibroma								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Ovarian cancer metastatic								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pancreatic neoplasm								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Prostate cancer								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Renal cell carcinoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Salivary gland neoplasm								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Seborrhoeic keratosis								
Normal	2	(0.4)	3	0.65	0			
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Uterine leiomyoma								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Nervous system disorders								
All								
Normal	63	(13.4)	84	18.07	59	(12.9)	76	16.85
Impaired	0				0			
Missing	2	(9.5)	3	14.52	8	(24.2)	9	27.23
Ageusia								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Anosmia								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Balance disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Brain injury								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Burning sensation								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Carotid arteriosclerosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Carpal tunnel syndrome								
Normal	4	(0.9)	4	0.86	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Cerebral atrophy								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Cerebral haemorrhage								
Normal	1	(0.2)	1	0.22	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Cerebrovascular disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Cervical radiculopathy								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	12	(2.6)	16	3.44	12	(2.6)	13	2.88
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Dizziness postural								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Dysgeusia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Headache								
Normal	15	(3.2)	17	3.66	14	(3.1)	21	4.66
Impaired	0				0			
Missing	1	(4.8)	1	4.84	3	(9.1)	3	9.08
Hypoaesthesia								
Normal	5	(1.1)	7	1.51	3	(0.7)	4	0.89
Impaired	0				0			
Missing	0				0			
Lethargy								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Lumbar radiculopathy								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Memory impairment								
Normal	1	(0.2)	1	0.22	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Mental impairment								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Neuralgia								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Neuroglycopenia								
Normal	1	(0.2)	1	0.22	1	(0.2)	3	0.67
Impaired	0				0			
Missing	0				0			
Neuropathy peripheral								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Paraesthesia								
Normal	4	(0.9)	4	0.86	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Parkinsonian gait								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Post herpetic neuralgia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Presyncope								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Sciatica								
Normal	3	(0.6)	3	0.65	4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				2	(6.1)	3	9.08
Somnolence								
Normal	0				1	(0.2)	1	0.22

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Syncope								
Normal	5	(1.1)	5	1.08	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Tension headache								
Normal	2	(0.4)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Thrombotic stroke								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Transient ischaemic attack								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	5	(1.1)	6	1.29	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Trigeminal neuralgia								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Normal	15	(3.2)	16	3.44	9	(2.0)	9	2.00
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Anxiety								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Bruxism								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Depressed mood								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Depression								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Insomnia								
Normal	6	(1.3)	6	1.29	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Mood swings								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Nightmare								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Persistent depressive disorder								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Sleep disorder								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Normal	14	(3.0)	18	3.87	16	(3.5)	18	3.99
Impaired	0				0			
Missing	0				4	(12.1)	4	12.10
Acute kidney injury								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Calculus urinary								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Chronic kidney disease								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Diabetic nephropathy								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Dysuria								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Haematuria								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Microalbuminuria								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Nephrolithiasis								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Nocturia								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pollakiuria								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Pyelocaliectasis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Renal colic								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Renal impairment								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Ureterolithiasis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Urinary incontinence								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Urinary retention								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Urinary tract obstruction								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Urine odour abnormal								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Reproductive system and breast disorders								
All								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	9	(1.9)	9	1.94	4	(0.9)	6	1.33
Impaired	0				0			
Missing	1	(4.8)	1	4.84	3	(9.1)	3	9.08
Atrophic vulvovaginitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Benign prostatic hyperplasia								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Breast mass								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Breast pain								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Erectile dysfunction								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Galactorrhoea								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Menopausal symptoms								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Ovarian cyst								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Penile rash								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Pruritus genital								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Uterine polyp								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Uterine prolapse								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Vulvovaginal dryness								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vulvovaginal pruritus								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Respiratory, thoracic and mediastinal disorders								
All								
Normal	41	(8.7)	54	11.62	35	(7.6)	49	10.87
Impaired	0				0			
Missing	4	(19.0)	5	24.20	3	(9.1)	3	9.08
Acquired diaphragmatic eventration								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Acute pulmonary oedema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Acute respiratory failure								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Allergic bronchitis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Asthma								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Bronchiectasis								
Normal	1	(0.2)	1	0.22	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Bronchitis chronic								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Chronic obstructive pulmonary disease								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Cough								
Normal	9	(1.9)	9	1.94	8	(1.7)	9	2.00
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Dyspnoea								
Normal	0				5	(1.1)	5	1.11
Impaired	0				0			
Missing	0				0			
Dyspnoea exertional								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Emphysema								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Epistaxis								
Normal	0				1	(0.2)	2	0.44
Impaired	0				0			
Missing	0				0			
Haemoptysis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Interstitial lung disease								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Laryngeal cyst								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Nasal congestion								
Normal	4	(0.9)	4	0.86	2	(0.4)	2	0.44

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Nasal dryness								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	8	(1.7)	9	1.94	4	(0.9)	5	1.11
Impaired	0				0			
Missing	2	(9.5)	2	9.68	3	(9.1)	3	9.08
Paranasal sinus discomfort								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pleural effusion								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pleuritic pain								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Productive cough								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Pulmonary embolism								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Pulmonary fibrosis								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Pulmonary mass								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Respiratory disorder								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Respiratory failure								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Rhinitis allergic								
Normal	0				1	(0.2)	5	1.11
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	3	(0.6)	3	0.65	3	(0.7)	3	0.67
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Sinus congestion								
Normal	1	(0.2)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Sinus pain								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Sleep apnoea syndrome								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Sneezing								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Throat irritation								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Upper-airway cough syndrome								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	42	(8.9)	44	9.46	37	(8.1)	48	10.64
Impaired	0				0			
Missing	0				5	(15.2)	7	21.18

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Actinic keratosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Alopecia								
Normal	3	(0.6)	3	0.65	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Alopecia areata								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Angioedema								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Asteatosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Blister								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Cold sweat								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Cold urticaria								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dermal cyst								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Dermatitis								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Dermatitis allergic								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatitis contact								
Normal	5	(1.1)	6	1.29	6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Diabetic foot								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Drug eruption								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Dry skin								
Normal	3	(0.6)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Ecchymosis								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	5	(1.1)	5	1.08	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Erythema								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Granuloma annulare								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Haemorrhage subcutaneous								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hyperhidrosis								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hyperkeratosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ingrowing nail								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Lentigo								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Lipodystrophy acquired								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Lipohypertrophy								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Macule								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Miliaria								
Normal	0				2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				2	(6.1)	2	6.05
Myxoid cyst								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Night sweats								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	2	(0.4)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Psoriasis								
Normal	2	(0.4)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Purpura								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rash								
Normal	2	(0.4)	2	0.43	6	(1.3)	6	1.33
Impaired	0				0			
Missing	0				0			
Skin exfoliation								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Skin fissures								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Skin irritation								
Normal	2	(0.4)	3	0.65	0			
Impaired	0				0			
Missing	0				0			
Skin lesion								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Skin ulcer								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Urticaria								
Normal	0				4	(0.9)	4	0.89
Impaired	0				0			
Missing	0				0			
Urticaria contact								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Urticaria thermal								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	1	(4.8)	1	4.84	1	(3.0)	1	3.03
Knee operation								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Large intestinal polypectomy								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	3.03
Removal of foreign body								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Vascular disorders								
All								
Normal	31	(6.6)	36	7.74	25	(5.5)	29	6.43
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Aortic arteriosclerosis								
Normal	2	(0.4)	2	0.43	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Aortic stenosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Arteriosclerosis								
Normal	1	(0.2)	1	0.22	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			
Blood pressure inadequately controlled								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Brachiocephalic arteriosclerosis								
Normal	1	(0.2)	1	0.22	3	(0.7)	3	0.67
Impaired	0				0			
Missing	0				0			
Flushing								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Haematoma								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	12	(2.6)	12	2.58	10	(2.2)	11	2.44
Impaired	0				0			
Missing	1	(4.8)	1	4.84	0			
Hypertensive crisis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Hypertensive urgency								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Hypotension								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Iliac artery stenosis								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Intermittent claudication								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Macroangiopathy								
Normal	0				1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Peripheral arterial occlusive disease								
Normal	1	(0.2)	2	0.43	2	(0.4)	2	0.44
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery occlusion								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Peripheral artery stenosis								
Normal	1	(0.2)	2	0.43	0			
Impaired	0				0			
Missing	0				0			
Peripheral coldness								
Normal	3	(0.6)	3	0.65	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Peripheral vascular disorder								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Peripheral venous disease								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			
Superficial vein thrombosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Thrombosis								
Normal	1	(0.2)	1	0.22	0			
Impaired	0				0			
Missing	0				0			
Varicose vein								
Normal	1	(0.2)	1	0.22	1	(0.2)	1	0.22
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IGlar U100.

7.16.54 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	251				246			
Impaired	0				0			
Missing	11				17			
PYE (years)								
Normal	148.85				143.85			
Impaired	0				0			
Missing	6.39				8.92			
Events								
Normal	153	(61.0)	427	286.86	128	(52.0)	317	220.36
Impaired	0				0			
Missing	8	(72.7)	39	610.05	6	(35.3)	11	123.36
Blood and lymphatic system disorders								
All								
Normal	1	(0.4)	3	2.02	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Anaemia								
Normal	1	(0.4)	3	2.02	0			
Impaired	0				0			
Missing	0				0			
Thrombocytosis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Normal	5	(2.0)	7	4.70	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Acute myocardial infarction								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Atrial fibrillation								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Bradycardia								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Cardiac failure congestive								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Cardiac flutter								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Coronary artery disease								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Myocardial infarction								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Supraventricular tachycardia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	4	(1.6)	4	2.69	4	(1.6)	4	2.78
Impaired	0				0			
Missing	0				0			
Deafness unilateral								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Ear pain								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hypoacusis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tinnitus								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	0				3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Adrenocortical insufficiency acute								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Inappropriate antidiuretic hormone secretion								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	27	(10.8)	31	20.83	24	(9.8)	29	20.16
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Astigmatism								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Cataract								
Normal	2	(0.8)	2	1.34	4	(1.6)	4	2.78
Impaired	0				0			
Missing	0				0			
Cataract nuclear								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Conjunctival haemorrhage								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	2	(0.8)	2	1.34	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Diabetic retinopathy								
Normal	10	(4.0)	11	7.39	16	(6.5)	17	11.82

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Dry age-related macular degeneration								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Dry eye								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Epiretinal membrane								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Eye irritation								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Glaucoma								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Lacrimation increased								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Myopia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Non-proliferative retinopathy								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Ocular hyperaemia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Ocular hypertension								
Normal	1	(0.4)	1	0.67	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Presbyopia								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Retinal exudates								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Retinal haemorrhage								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Retinal vein occlusion								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Visual acuity reduced								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Vitreous haemorrhage								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorders								
All								
Normal	32	(12.7)	53	35.61	31	(12.6)	41	28.50
Impaired	0				0			
Missing	6	(54.5)	7	109.50	1	(5.9)	1	11.21
Abdominal pain								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Abdominal pain lower								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Abdominal pain upper								
Normal	1	(0.4)	3	2.02	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Chronic gastritis								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	3	(1.2)	6	4.03	0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Dental caries								
Normal	0				2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Diarrhoea								
Normal	12	(4.8)	15	10.08	9	(3.7)	9	6.26
Impaired	0				0			
Missing	2	(18.2)	2	31.28	0			
Diverticulum								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Dyspepsia								
Normal	3	(1.2)	3	2.02	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Flatulence								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Food poisoning								
Normal	1	(0.4)	1	0.67	1	(0.4)	2	1.39
Impaired	0				0			
Missing	0				0			
Gastric dysplasia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Gastric mucosal hypertrophy								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastric polyps								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Gastritis								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Gastrointestinal angiodysplasia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								
Normal	1	(0.4)	1	0.67	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Gingival bleeding								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Haemorrhoids								
Normal	1	(0.4)	1	0.67	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Hiatus hernia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Hyperaesthesia teeth								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Intra-abdominal haematoma								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Large intestine polyp								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	6	(2.4)	6	4.03	6	(2.4)	6	4.17
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Pancreatic pseudocyst								
Normal	0				1	(0.4)	1	0.70

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Periodontal disease								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Tongue rough								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Toothache								
Normal	1	(0.4)	1	0.67	3	(1.2)	5	3.48
Impaired	0				0			
Missing	0				0			
Vomiting								
Normal	3	(1.2)	3	2.02	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
General disorders and administration site conditions								
All								
Normal	24	(9.6)	34	22.84	18	(7.3)	20	13.90
Impaired	0				0			
Missing	1	(9.1)	2	31.28	1	(5.9)	1	11.21
Asthenia								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Chest discomfort								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Chest pain								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Chills								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Condition aggravated								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fatigue								
Normal	2	(0.8)	3	2.02	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Hunger								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Influenza like illness								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Injection site reaction								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Injection site swelling								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	2	(0.8)	2	1.34	2	(0.8)	3	2.09
Impaired	0				0			
Missing	0				0			
Medical device site bruise								
Normal	1	(0.4)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Medical device site dermatitis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Medical device site erythema								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Medical device site pruritus								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Medical device site rash								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Medical device site reaction								
Normal	1	(0.4)	1	0.67	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Oedema peripheral								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Pain								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pyrexia								
Normal	5	(2.0)	5	3.36	6	(2.4)	6	4.17
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Vaccination site pain								
Normal	3	(1.2)	4	2.69	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Hepatobiliary disorders								
All								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Alcoholic liver disease								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Gallbladder polyp								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Hepatic cirrhosis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	1	(0.4)	1	0.67	4	(1.6)	4	2.78
Impaired	0				0			
Missing	1	(9.1)	1	15.64	1	(5.9)	1	11.21
Allergy to arthropod bite								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Allergy to arthropod sting								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Anaphylactic reaction								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	0				2	(0.8)	2	1.39
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Infections and infestations								
All								
Normal	72	(28.7)	93	62.48	48	(19.5)	65	45.18
Impaired	0				0			
Missing	4	(36.4)	5	78.21	1	(5.9)	1	11.21
Abscess limb								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Anal abscess								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Campylobacter gastroenteritis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cellulitis								
Normal	1	(0.4)	1	0.67	1	(0.4)	2	1.39
Impaired	0				0			
Missing	0				0			
Conjunctivitis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	8	(3.2)	8	5.37	7	(2.8)	7	4.87
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
COVID-19 pneumonia								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Cystitis								
Normal	1	(0.4)	1	0.67	2	(0.8)	3	2.09
Impaired	0				0			
Missing	0				0			
Ear infection								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Enteritis infectious								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Eye infection								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Folliculitis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Fungal infection								
Normal	1	(0.4)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Fungal skin infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis								
Normal	5	(2.0)	5	3.36	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Gastrointestinal infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Helicobacter infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Herpes zoster								
Normal	0				3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	1	(0.4)	1	0.67	4	(1.6)	5	3.48
Impaired	0				0			
Missing	0				0			
Kidney infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Localised infection								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	21	(8.4)	27	18.14	10	(4.1)	14	9.73
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Onychomycosis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	3	(1.2)	3	2.02	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paraspinal abscess								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Peritonsillar abscess								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pneumonia								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Pulpitis dental								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pustule								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Rhinitis								
Normal	0				1	(0.4)	3	2.09
Impaired	0				0			
Missing	0				0			
Sinusitis								
Normal	2	(0.8)	2	1.34	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Soft tissue infection								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Subcutaneous abscess								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tinea pedis								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Tinea versicolour								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tonsillitis								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	0				3	(1.2)	3	2.09
Impaired	0				0			
Missing	1	(9.1)	2	31.28	0			
Upper respiratory tract infection								
Normal	8	(3.2)	11	7.39	4	(1.6)	4	2.78
Impaired	0				0			
Missing	0				0			
Urinary tract infection								
Normal	4	(1.6)	5	3.36	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Vaginal infection								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Varicella zoster virus infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Vulvitis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Vulvovaginal candidiasis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Wound infection								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Injury, poisoning and procedural complications								
All								
Normal	25	(10.0)	32	21.50	21	(8.5)	25	17.38

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	2	(18.2)	7	109.50	1	(5.9)	1	11.21
Accidental overdose								
Normal	4	(1.6)	4	2.69	0			
Impaired	0				0			
Missing	0				0			
Arthropod bite								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Arthropod sting								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Bone contusion								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Craniocerebral injury								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Face injury								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Facial bones fracture								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Fall								
Normal	5	(2.0)	5	3.36	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Foot fracture								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hand fracture								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Heat illness								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Intentional overdose								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Joint injury								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Limb injury								
Normal	0				1	(0.4)	2	1.39
Impaired	0				0			
Missing	0				0			
Muscle contusion								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Muscle injury								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Overdose								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Rib fracture								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Road traffic accident								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Skin abrasion								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Skin laceration								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Stab wound								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Subcutaneous haematoma								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tendon injury								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Tendon rupture								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Thermal burn								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tibia fracture								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Underdose								
Normal	1	(0.4)	1	0.67	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Vaccination complication								
Normal	2	(0.8)	2	1.34	3	(1.2)	3	2.09
Impaired	0				0			
Missing	2	(18.2)	6	93.85	0			
Wound								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Wrist fracture								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations								
All								
Normal	5	(2.0)	5	3.36	3	(1.2)	4	2.78
Impaired	0				0			
Missing	0				0			
Alanine aminotransferase increased								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Blood creatinine increased								
Normal	3	(1.2)	3	2.02	0			
Impaired	0				0			
Missing	0				0			
Blood potassium increased								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Intraocular pressure increased								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Liver function test abnormal								
Normal	0				1	(0.4)	2	1.39
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Normal	6	(2.4)	6	4.03	11	(4.5)	16	11.12
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Abnormal weight gain								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Hyperammonaemia								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hypercholesterolaemia								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hyperglycaemia								
Normal	1	(0.4)	1	0.67	2	(0.8)	2	1.39
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Hyperkalaemia								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hyperlipidaemia								
Normal	1	(0.4)	1	0.67	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				0			
Hyperuricaemia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	1	(0.4)	1	0.67	3	(1.2)	8	5.56
Impaired	0				0			
Missing	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	34	(13.5)	54	36.28	28	(11.4)	42	29.20
Impaired	0				0			
Missing	4	(36.4)	6	93.85	1	(5.9)	3	33.64

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthralgia								
Normal	4	(1.6)	4	2.69	9	(3.7)	12	8.34
Impaired	0				0			
Missing	2	(18.2)	3	46.93	1	(5.9)	1	11.21
Arthritis								
Normal	1	(0.4)	1	0.67	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Axillary mass								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Back pain								
Normal	6	(2.4)	6	4.03	10	(4.1)	11	7.65
Impaired	0				0			
Missing	1	(9.1)	1	15.64	1	(5.9)	2	22.43
Bursitis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Flank pain								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Intervertebral disc disorder								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Intervertebral disc protrusion								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Muscle spasms								
Normal	8	(3.2)	10	6.72	1	(0.4)	1	0.70
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Musculoskeletal stiffness								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Myalgia								
Normal	4	(1.6)	4	2.69	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Osteoarthritis								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Osteoporosis								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Pain in extremity								
Normal	3	(1.2)	3	2.02	5	(2.0)	6	4.17
Impaired	0				0			
Missing	0				0			
Periarthritis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Plantar fasciitis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Polymyalgia rheumatica								
Normal	1	(0.4)	1	0.67	1	(0.4)	3	2.09
Impaired	0				0			
Missing	0				0			
Rheumatoid arthritis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Rotator cuff syndrome								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Soft tissue swelling								
Normal	1	(0.4)	3	2.02	0			
Impaired	0				0			
Missing	0				0			
Spinal stenosis								
Normal	2	(0.8)	4	2.69	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 2" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendonitis								
Normal	2	(0.8)	4	2.69	0			
Impaired	0				0			
Missing	0				0			
Tenosynovitis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Trigger finger								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	3	(1.2)	3	2.02	3	(1.2)	3	2.09
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Breast cancer								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Chronic myeloid leukaemia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Colon adenoma								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Colon cancer stage II								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Gastric cancer								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Lymphangioma								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pancreatic carcinoma metastatic								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(5.9)	1	11.21
Nervous system disorders								
All								
Normal	23	(9.2)	37	24.86	24	(9.8)	33	22.94
Impaired	0				0			
Missing	4	(36.4)	5	78.21	1	(5.9)	1	11.21
Autonomic nervous system imbalance								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Burning sensation								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Carotid artery aneurysm								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Carpal tunnel syndrome								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Cerebral infarction								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Cervicobrachial syndrome								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	4	(1.6)	5	3.36	9	(3.7)	13	9.04
Impaired	0				0			
Missing	0				0			
Facial paralysis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Headache								
Normal	11	(4.4)	16	10.75	8	(3.3)	9	6.26
Impaired	0				0			
Missing	3	(27.3)	4	62.57	1	(5.9)	1	11.21
Hypoaesthesia								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neuralgia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Neuropathy peripheral								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Peripheral paralysis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Piriformis syndrome								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Post herpetic neuralgia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Restless legs syndrome								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Sciatica								
Normal	2	(0.8)	2	1.34	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Somnolence								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Syncope								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Tension headache								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Thalamic infarction								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thrombotic stroke								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	0				2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Psychiatric disorders								
All								
Normal	3	(1.2)	4	2.69	5	(2.0)	5	3.48
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Adjustment disorder								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Depression								
Normal	1	(0.4)	1	0.67	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Insomnia								
Normal	3	(1.2)	3	2.02	0			
Impaired	0				0			
Missing	0				0			
Major depression								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Sleep disorder								
Normal	0				2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Renal and urinary disorders								
All								
Normal	8	(3.2)	10	6.72	0			
Impaired	0				0			
Missing	0				0			
Bladder prolapse								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic nephropathy								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Hydronephrosis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Nephrotic syndrome								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Pollakiuria								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Polyuria								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Renal impairment								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Urethral stenosis								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Urine odour abnormal								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	4	(1.6)	4	2.69	2	(0.8)	2	1.39
Impaired	0				0			
Missing	0				0			
Benign prostatic hyperplasia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Cervical polyp								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Erectile dysfunction								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Prostatitis								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pruritus genital								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	12	(4.8)	25	16.79	4	(1.6)	5	3.48
Impaired	0				0			
Missing	3	(27.3)	4	62.57	0			
Acute respiratory failure								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Chronic obstructive pulmonary disease								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Cough								
Normal	1	(0.4)	2	1.34	0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epistaxis								
Normal	3	(1.2)	7	4.70	0			
Impaired	0				0			
Missing	0				0			
Nasal congestion								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Nasal obstruction								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Nasal septum deviation								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	0				2	(0.8)	3	2.09
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Productive cough								
Normal	2	(0.8)	2	1.34	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Respiratory failure								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	5	(2.0)	7	4.70	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Sleep apnoea syndrome								
Normal	0				0			
Impaired	0				0			
Missing	1	(9.1)	1	15.64	0			
Sneezing								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	13	(5.2)	14	9.41	6	(2.4)	6	4.17
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Alopecia								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Blister								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Dermal cyst								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Dermatitis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Hyperhidrosis								
Normal	1	(0.4)	1	0.67	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Miliaria								
Normal	2	(0.8)	2	1.34	0			
Impaired	0				0			
Missing	0				0			
Neurodermatitis								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			
Rash								
Normal	3	(1.2)	3	2.02	1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Rash papular								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 2 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urticaria								
Normal	3	(1.2)	3	2.02	0			
Impaired	0				0			
Missing	0				0			
Surgical and medical procedures								
All								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Toe amputation								
Normal	0				1	(0.4)	1	0.70
Impaired	0				0			
Missing	0				0			
Vascular disorders								
All								
Normal	5	(2.0)	5	3.36	5	(2.0)	5	3.48
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	4	(1.6)	4	2.69	5	(2.0)	5	3.48
Impaired	0				0			
Missing	0				0			
Orthostatic hypotension								
Normal	1	(0.4)	1	0.67	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.16.55 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on- treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	273				279			
Impaired	2				2			
Missing	16				10			
PYE (years)								
Normal	156.77				159.72			
Impaired	1.05				1.14			
Missing	9.54				5.94			
Events								
Normal	162	(59.3)	428	273.00	158	(56.6)	522	326.83
Impaired	2	(100.0)	8	764.92	2	(100.0)	5	437.95
Missing	7	(43.8)	19	199.13	7	(70.0)	23	387.13
Blood and lymphatic system disorders								
All								
Normal	6	(2.2)	6	3.83	3	(1.1)	3	1.88
Impaired	1	(50.0)	1	95.62	1	(50.0)	1	87.59
Missing	0				1	(10.0)	1	16.83
Anaemia								
Normal	3	(1.1)	3	1.91	1	(0.4)	1	0.63
Impaired	0				1	(50.0)	1	87.59
Missing	0				1	(10.0)	1	16.83
Blood loss anaemia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Eosinophilia								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Iron deficiency anaemia								
Normal	0				1	(0.4)	1	0.63
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Lymphadenopathy mediastinal								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	7	(2.6)	8	5.10	13	(4.7)	21	13.15
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Acute myocardial infarction								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Angina pectoris								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Aortic valve calcification								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Aortic valve sclerosis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Atrial enlargement								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Atrial fibrillation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bundle branch block left								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bundle branch block right								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Cardiac failure								
Normal	0				1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Cardiac failure congestive								
Normal	0				2	(0.7)	3	1.88
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac perfusion defect								
Normal	0				1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Coronary artery disease								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Left atrial enlargement								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Left ventricular hypertrophy								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Myocardial infarction								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Myocardial ischaemia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Palpitations								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Pericarditis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Sinus bradycardia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Tachycardia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Corneal dystrophy								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Ear and labyrinth disorders								
All								
Normal	1	(0.4)	1	0.64	4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Cerumen impaction								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Ear discomfort								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Middle ear inflammation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Adrenocortical insufficiency acute								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypogonadism								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	25	(9.2)	32	20.41	37	(13.3)	55	34.44
Impaired	0				0			
Missing	1	(6.3)	1	10.48	1	(10.0)	2	33.66
Age-related macular degeneration								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Astigmatism								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cataract								
Normal	2	(0.7)	2	1.28	3	(1.1)	4	2.50
Impaired	0				0			
Missing	0				1	(10.0)	2	33.66
Corneal erosion								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	2	(0.7)	2	1.28	3	(1.1)	4	2.50
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinopathy								
Normal	11	(4.0)	13	8.29	15	(5.4)	15	9.39
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Diplopia								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Eye discharge								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Eye inflammation								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Eye pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Macular degeneration								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	3	(1.1)	3	1.91	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Meibomianitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Open angle glaucoma								
Normal	0				1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Presbyopia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Retinal deposits								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal detachment								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Retinal drusen								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Retinal exudates								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Retinal haemorrhage								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Retinal scar								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Retinal vascular disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Retinopathy hypertensive								
Normal	2	(0.7)	2	1.28	4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Visual impairment								
Normal	0				1	(0.4)	9	5.64
Impaired	0				0			
Missing	0				0			
Vitreous detachment								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Vitreous haemorrhage								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal disorders								
All								
Normal	32	(11.7)	45	28.70	35	(12.5)	49	30.68
Impaired	1	(50.0)	1	95.62	0			
Missing	2	(12.5)	4	41.92	0			
Abdominal discomfort								
Normal	1	(0.4)	1	0.64	1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Abdominal distension								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Abdominal pain								
Normal	2	(0.7)	2	1.28	5	(1.8)	6	3.76
Impaired	0				0			
Missing	0				0			
Abdominal pain upper								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Chronic gastritis								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	2	(0.7)	2	1.28	3	(1.1)	3	1.88
Impaired	0				0			
Missing	0				0			
Dental caries								
Normal	0				4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Diarrhoea								
Normal	13	(4.8)	15	9.57	9	(3.2)	9	5.64
Impaired	0				0			
Missing	2	(12.5)	3	31.44	0			
Eructation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Faeces pale								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Food poisoning								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gastrointestinal haemorrhage								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Gingival disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypoaesthesia oral								
Normal	2	(0.7)	4	2.55	0			
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	4	(1.5)	4	2.55	4	(1.4)	4	2.50
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Pancreatic duct dilatation								
Normal	0				0			
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Pancreatic failure								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Pancreatitis chronic								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Periodontal disease								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Proctalgia								
Normal	1	(0.4)	1	0.64	0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Toothache								
Normal	1	(0.4)	1	0.64	3	(1.1)	4	2.50
Impaired	0				0			
Missing	0				0			
Upper gastrointestinal haemorrhage								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Vomiting								
Normal	7	(2.6)	9	5.74	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
General disorders and administration site conditions								
All								
Normal	23	(8.4)	33	21.05	25	(9.0)	28	17.53
Impaired	0				0			
Missing	3	(18.8)	5	52.40	1	(10.0)	8	134.65
Asthenia								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Axillary pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Chest pain								
Normal	3	(1.1)	3	1.91	0			
Impaired	0				0			
Missing	0				0			
Cyst								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Discomfort								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(10.0)	8	134.65
Facial pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fatigue								
Normal	4	(1.5)	5	3.19	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Feeling abnormal								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Inflammation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Injection site pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Injection site rash								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Injection site reaction								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	2	(0.7)	2	1.28	1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Medical device site dermatitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Medical device site erythema								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Medical device site pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Medical device site reaction								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Multiple organ dysfunction syndrome								
Normal	1	(0.4)	1	0.64	0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Oedema								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Oedema due to renal disease								
Normal	0				0			
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Oedema peripheral								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Pain								
Normal	3	(1.1)	4	2.55	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Peripheral swelling								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Pyrexia								
Normal	1	(0.4)	1	0.64	6	(2.2)	7	4.38
Impaired	0				0			
Missing	2	(12.5)	2	20.96	0			
Thirst								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Vaccination site inflammation								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Vaccination site pain								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Vaccination site pruritus								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Xerosis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
Normal	1	(0.4)	2	1.28	4	(1.4)	6	3.76
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Biliary dyskinesia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cholecystitis chronic								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gallbladder polyp								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hepatic function abnormal								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hepatic steatosis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hepatomegaly								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hyperplastic cholecystopathy								
Normal	0				0			
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Liver disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	3	(1.1)	3	1.91	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Drug hypersensitivity								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hypersensitivity								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Infections and infestations								
All								
Normal	84	(30.8)	113	72.08	76	(27.2)	116	72.63
Impaired	1	(50.0)	2	191.23	1	(50.0)	1	87.59
Missing	2	(12.5)	2	20.96	2	(20.0)	3	50.50
Abscess								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Asymptomatic COVID-19								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bacteraemia								
Normal	0				0			
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Breast abscess								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	8	(2.9)	8	5.10	3	(1.1)	3	1.88
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Candida infection								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cellulitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cholecystitis infective								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Conjunctivitis								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Coronavirus infection								
Normal	0				1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	26	(9.5)	26	16.58	23	(8.2)	25	15.65
Impaired	0				0			
Missing	0				0			
COVID-19 pneumonia								
Normal	4	(1.5)	4	2.55	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cystitis								
Normal	2	(0.7)	2	1.28	3	(1.1)	3	1.88
Impaired	0				0			
Missing	0				0			
Diabetic foot infection								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Eye infection								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Fungal infection								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fungal skin infection								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gastroenteritis								
Normal	7	(2.6)	7	4.47	5	(1.8)	6	3.76
Impaired	0				0			
Missing	0				0			
Gastroenteritis viral								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Herpes zoster								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Infected dermal cyst								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	5	(1.8)	5	3.19	7	(2.5)	9	5.64
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Laryngitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Localised infection								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	8	(2.9)	8	5.10	12	(4.3)	15	9.39
Impaired	0				0			
Missing	0				0			
Oral herpes								
Normal	1	(0.4)	2	1.28	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Osteomyelitis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Otitis media acute								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Paronychia								
Normal	1	(0.4)	1	0.64	1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Periodontitis								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Pharyngitis								
Normal	3	(1.1)	3	1.91	5	(1.8)	5	3.13
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Pharyngotonsillitis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Pneumonia								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	1	(50.0)	1	95.62	0			
Missing	1	(6.3)	1	10.48	0			
Pneumonia viral								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Post procedural infection								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Pulmonary tuberculoma								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulpitis dental								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Respiratory syncytial virus infection								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection								
Normal	3	(1.1)	3	1.91	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Respiratory tract infection viral								
Normal	6	(2.2)	7	4.47	5	(1.8)	6	3.76
Impaired	0				0			
Missing	0				0			
Sepsis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Sinusitis								
Normal	3	(1.1)	4	2.55	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Soft tissue infection								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	2	(0.7)	2	1.28	2	(0.7)	3	1.88
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Upper respiratory tract infection								
Normal	5	(1.8)	5	3.19	5	(1.8)	5	3.13
Impaired	1	(50.0)	1	95.62	1	(50.0)	1	87.59
Missing	0				0			
Urinary tract infection								
Normal	3	(1.1)	3	1.91	5	(1.8)	7	4.38
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral infection								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Viral rhinitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Viral tracheitis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Vulvovaginal mycotic infection								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Injury, poisoning and procedural complications								
All								
Normal	19	(7.0)	25	15.95	26	(9.3)	34	21.29
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Accidental overdose								
Normal	1	(0.4)	1	0.64	2	(0.7)	3	1.88
Impaired	0				0			
Missing	0				0			
Accidental underdose								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Animal bite								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Arthropod bite								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Arthropod sting								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Chillblains								
Normal	1	(0.4)	1	0.64	0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Concussion								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Crush injury								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Exposure to SARS-CoV-2								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Extra dose administered								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Fall								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Foot fracture								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Incorrect dose administered								
Normal	3	(1.1)	3	1.91	1	(0.4)	2	1.25
Impaired	0				0			
Missing	0				0			
Joint injury								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Limb injury								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medication error								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Meniscus injury								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Muscle injury								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Muscle strain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Overdose								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Product administration error								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Skin abrasion								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Skin laceration								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Spinal column injury								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Spinal compression fracture								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Subcutaneous haematoma								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Subdural haematoma								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Thermal burn								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Tooth fracture								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Vaccination complication								
Normal	0				4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Wound								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Wrong product administered								
Normal	1	(0.4)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Investigations								
All								
Normal	12	(4.4)	15	9.57	13	(4.7)	14	8.77
Impaired	0				0			
Missing	0				0			
Amylase increased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Blood alkaline phosphatase increased								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Blood creatinine increased								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Blood pressure increased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood triglycerides increased								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Blood urine present								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Catheterisation cardiac								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Electrocardiogram abnormal								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Electrocardiogram T wave inversion								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Eosinophil count increased								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Glomerular filtration rate decreased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Haematocrit increased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Haemoglobin increased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Liver function test abnormal								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Liver function test increased								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Platelet count decreased								
Normal	0				1	(0.4)	1	0.63

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Transaminases increased								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Weight increased								
Normal	6	(2.2)	6	3.83	4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Metabolism and nutrition disorders								
All								
Normal	13	(4.8)	16	10.21	19	(6.8)	21	13.15
Impaired	1	(50.0)	1	95.62	1	(50.0)	1	87.59
Missing	1	(6.3)	1	10.48	0			
Decreased appetite								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Dehydration								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Dyslipidaemia								
Normal	2	(0.7)	3	1.91	3	(1.1)	3	1.88
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Fluid retention								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hypercholesterolaemia								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hyperglycaemia								
Normal	0				4	(1.4)	4	2.50
Impaired	0				1	(50.0)	1	87.59
Missing	0				0			
Hyperkalaemia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				4	(1.4)	4	2.50
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Hypertriglyceridaemia								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Hypoalbuminaemia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	3	(1.1)	3	1.91	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Hypokalaemia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Hyponatraemia								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Increased appetite								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Lipomatosis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Vitamin D deficiency								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	31	(11.4)	40	25.51	33	(11.8)	45	28.18
Impaired	0				1	(50.0)	2	175.18
Missing	1	(6.3)	1	10.48	1	(10.0)	1	16.83
Arthralgia								
Normal	5	(1.8)	6	3.83	6	(2.2)	6	3.76
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthritis								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Back disorder								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Back pain								
Normal	8	(2.9)	8	5.10	11	(3.9)	11	6.89
Impaired	0				0			
Missing	0				0			
Bone cyst								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bone pain								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Coccydynia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Flank pain								
Normal	0				0			
Impaired	0				1	(50.0)	1	87.59
Missing	0				0			
Foot deformity								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Intervertebral disc protrusion								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Jaw disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Muscle spasms								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				1	(50.0)	1	87.59
Missing	0				0			
Myalgia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Myositis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Neck pain								
Normal	4	(1.5)	4	2.55	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Osteoarthritis								
Normal	5	(1.8)	5	3.19	7	(2.5)	8	5.01
Impaired	0				0			
Missing	0				0			
Osteochondrosis								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Pain in extremity								
Normal	1	(0.4)	1	0.64	2	(0.7)	3	1.88
Impaired	0				0			
Missing	0				0			
Periarthritis								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Periostitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Rotator cuff syndrome								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Spinal osteoarthritis								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Tendon disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Tendonitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Tenosynovitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Torticollis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Trigger finger								
Normal	3	(1.1)	3	1.91	0			
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	4	(1.5)	4	2.55	3	(1.1)	5	3.13
Impaired	0				0			
Missing	0				0			
Adrenal adenoma								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Eye naevus								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Lung adenocarcinoma								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Osteoma								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Pancreatic neoplasm								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Small cell lung cancer								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Small intestine neuroendocrine tumour								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Uterine cancer								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Uterine leiomyoma								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Nervous system disorders								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	18	(6.6)	30	19.14	29	(10.4)	47	29.43
Impaired	0				0			
Missing	1	(6.3)	2	20.96	0			
Anosmia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Basilar migraine								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Carpal tunnel syndrome								
Normal	2	(0.7)	2	1.28	4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Cerebral arteriosclerosis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Cerebrovascular accident								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cerebrovascular disorder								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Cognitive disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	5	(1.8)	9	5.74	2	(0.7)	3	1.88
Impaired	0				0			
Missing	0				0			
Dizziness postural								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dysgeusia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Essential tremor								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Facial nerve disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Headache								
Normal	7	(2.6)	8	5.10	9	(3.2)	12	7.51
Impaired	0				0			
Missing	1	(6.3)	2	20.96	0			
Hemiparesis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypoaesthesia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypoglycaemic coma								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hyporeflexia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Memory impairment								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Morton's neuralgia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neuropathy peripheral								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Paraesthesia								
Normal	0				3	(1.1)	3	1.88
Impaired	0				0			
Missing	0				0			
Sciatica								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Sleep deficit								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Transient ischaemic attack								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	1	(0.4)	1	0.64	2	(0.7)	6	3.76
Impaired	0				0			
Missing	0				0			
Vascular encephalopathy								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Normal	2	(0.7)	2	1.28	8	(2.9)	8	5.01
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Affect lability								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Depression								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Fear								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Insomnia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Mental status changes								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Mixed anxiety and depressive disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Phobia								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Sleep disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Normal	3	(1.1)	6	3.83	4	(1.4)	4	2.50
Impaired	1	(50.0)	1	95.62	0			
Missing	0				2	(20.0)	2	33.66
Acute kidney injury								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Chronic kidney disease								
Normal	2	(0.7)	2	1.28	0			
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Dysuria								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Haematuria								
Normal	1	(0.4)	2	1.28	0			
Impaired	0				0			
Missing	0				0			
Hydrocalyx								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Nephropathy								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Renal colic								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	0				1	(0.4)	1	0.63
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Benign prostatic hyperplasia								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Menopausal disorder								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	15	(5.5)	18	11.48	19	(6.8)	23	14.40
Impaired	0				0			
Missing	2	(12.5)	2	20.96	0			
Asthma								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Bronchitis chronic								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cough								
Normal	3	(1.1)	3	1.91	4	(1.4)	4	2.50
Impaired	0				0			
Missing	0				0			
Dyspnoea								
Normal	1	(0.4)	1	0.64	5	(1.8)	6	3.76
Impaired	0				0			
Missing	0				0			
Emphysema								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Epistaxis								
Normal	1	(0.4)	1	0.64	1	(0.4)	2	1.25
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nasal congestion								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Nasal septum deviation								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	1	(6.3)	1	10.48	0			
Paranasal cyst								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Pleurisy								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Pulmonary fibrosis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Pulmonary hypertension								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Respiratory disorder								
Normal	3	(1.1)	3	1.91	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Rhinitis allergic								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Sinus congestion								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus pain								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	10	(3.7)	11	7.02	13	(4.7)	14	8.77
Impaired	1	(50.0)	1	95.62	0			
Missing	1	(6.3)	1	10.48	2	(20.0)	2	33.66
Alopecia								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Blister								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cold sweat								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Dermatitis contact								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	1	(6.3)	1	10.48	1	(10.0)	1	16.83
Hyperhidrosis								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	1	(50.0)	1	95.62	0			
Missing	0				0			
Hyperkeratosis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Intertrigo								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lipohypertrophy								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	1	(0.4)	1	0.64	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				1	(10.0)	1	16.83
Rash								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Seborrhoea								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Skin reaction								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Skin ulcer								
Normal	2	(0.7)	2	1.28	2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Umbilical haematoma								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Urticaria								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Normal	2	(0.7)	2	1.28	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Cardiac pacemaker replacement								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Shoulder operation								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Tooth extraction								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Vascular disorders								
All								
Normal	8	(2.9)	12	7.65	16	(5.7)	19	11.90
Impaired	0				0			
Missing	0				0			
Aortic arteriosclerosis								
Normal	0				2	(0.7)	2	1.25
Impaired	0				0			
Missing	0				0			
Arteriosclerosis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Blood pressure fluctuation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Deep vein thrombosis								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Diabetic vascular disorder								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 4 - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haematoma								
Normal	1	(0.4)	1	0.64	1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	2	(0.7)	2	1.28	6	(2.2)	6	3.76
Impaired	0				0			
Missing	0				0			
Hypertensive crisis								
Normal	1	(0.4)	1	0.64	1	(0.4)	3	1.88
Impaired	0				0			
Missing	0				0			
Hypertensive urgency								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Hypotension								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Neovascularisation								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			
Orthostatic hypotension								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Peripheral arterial occlusive disease								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Peripheral artery stenosis								
Normal	1	(0.4)	3	1.91	0			
Impaired	0				0			
Missing	0				0			
Peripheral venous disease								
Normal	1	(0.4)	1	0.64	0			
Impaired	0				0			
Missing	0				0			
Thrombophlebitis								
Normal	0				1	(0.4)	1	0.63
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.16.56 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	281				285			
Impaired	1				0			
Missing	8				7			
PYE (years)								
Normal	137.79				140.61			
Impaired	0.50				0			
Missing	4.02				3.51			
Events								
Normal	181	(64.4)	479	347.63	183	(64.2)	590	419.60
Impaired	0				0			
Missing	8	(100.0)	28	697.14	7	(100.0)	29	826.23
Blood and lymphatic system disorders								
All								
Normal	3	(1.1)	3	2.18	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Anaemia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Iron deficiency anaemia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Lymphadenitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Lymphadenopathy								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Thrombocytopenia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	8	(2.8)	8	5.81	4	(1.4)	4	2.84
Impaired	0				0			
Missing	1	(12.5)	1	24.90	1	(14.3)	2	56.98
Angina pectoris								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Angina unstable								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Atrial fibrillation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Bundle branch block right								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cardiac failure								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cardiomegaly								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Cardiovascular disorder								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Myocardial ischaemia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Palpitations								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Ventricular extrasystoles								
Normal	3	(1.1)	3	2.18	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	2	(0.7)	2	1.45	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Deafness neurosensory								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Ear pain								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Endocrine disorders								
All								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	29	(10.3)	37	26.85	26	(9.1)	35	24.89
Impaired	0				0			
Missing	0				2	(28.6)	2	56.98
Arteriosclerotic retinopathy								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Astigmatism								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cataract								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	4	(1.4)	4	2.90	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Cataract nuclear								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Conjunctival haemorrhage								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Corneal erosion								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Diabetic retinopathy								
Normal	12	(4.3)	12	8.71	13	(4.6)	13	9.25
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Dry eye								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Epiretinal membrane								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Glaucoma								
Normal	1	(0.4)	1	0.73	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	3	(1.1)	4	2.90	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Myopia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Non-proliferative retinopathy								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.7)	2	1.45	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Ocular hypertension								
Normal	0				1	(0.4)	2	1.42
Impaired	0				0			
Missing	0				0			
Photopsia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Posterior capsule opacification								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Presbyopia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Pterygium								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Retinal vascular disorder								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Retinopathy								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Retinopathy hypertensive								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Vitreous detachment								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Vitreous floaters								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorders								
All								
Normal	25	(8.9)	37	26.85	23	(8.1)	38	27.03
Impaired	0				0			
Missing	1	(12.5)	1	24.90	1	(14.3)	3	85.47
Abdominal discomfort								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Abdominal distension								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Abdominal pain								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Abdominal pain upper								
Normal	3	(1.1)	3	2.18	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Anal fissure								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Chronic gastritis								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Dental caries								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Diarrhoea								
Normal	5	(1.8)	6	4.35	3	(1.1)	4	2.84
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				1	(14.3)	1	28.49
Diverticulum intestinal								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Dyspepsia								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Faeces soft								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Gastric polyps								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Gastritis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Gastritis erosive								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Gingival recession								
Normal	0				1	(0.4)	2	1.42
Impaired	0				0			
Missing	0				0			
Haemorrhoids								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hiatus hernia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Impaired gastric emptying								
Normal	1	(0.4)	2	1.45	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Irritable bowel syndrome								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Lumbar hernia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	4	(1.4)	4	2.90	7	(2.5)	7	4.98
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Odynophagia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Pancreatic failure								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Pneumatosis intestinalis								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Toothache								
Normal	2	(0.7)	2	1.45	3	(1.1)	5	3.56
Impaired	0				0			
Missing	0				0			
Vomiting								
Normal	6	(2.1)	6	4.35	4	(1.4)	4	2.84
Impaired	0				0			
Missing	1	(12.5)	1	24.90	1	(14.3)	1	28.49
General disorders and administration site conditions								
All								
Normal	39	(13.9)	48	34.84	33	(11.6)	82	58.32
Impaired	0				0			
Missing	2	(25.0)	2	49.80	1	(14.3)	1	28.49
Asthenia								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chest pain								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Fatigue								
Normal	4	(1.4)	5	3.63	1	(0.4)	1	0.71
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Hunger								
Normal	1	(0.4)	1	0.73	1	(0.4)	2	1.42
Impaired	0				0			
Missing	0				0			
Hyperthermia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Inflammation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Influenza like illness								
Normal	3	(1.1)	3	2.18	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Injection site mass								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Injection site pain								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Injection site urticaria								
Normal	1	(0.4)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	3	(1.1)	3	2.18	3	(1.1)	44	31.29
Impaired	0				0			
Missing	0				0			
Medical device site bruise								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site dermatitis								
Normal	3	(1.1)	3	2.18	3	(1.1)	4	2.84
Impaired	0				0			
Missing	0				0			
Medical device site erythema								
Normal	0				3	(1.1)	4	2.84
Impaired	0				0			
Missing	0				0			
Medical device site haematoma								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Medical device site haemorrhage								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Medical device site irritation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Medical device site pain								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Medical device site pruritus								
Normal	1	(0.4)	1	0.73	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Medical device site rash								
Normal	6	(2.1)	6	4.35	6	(2.1)	6	4.27
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Medical device site reaction								
Normal	3	(1.1)	3	2.18	0			
Impaired	0				0			
Missing	0				0			
Oedema peripheral								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Pain								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pyrexia								
Normal	9	(3.2)	10	7.26	6	(2.1)	6	4.27
Impaired	0				0			
Missing	0				0			
Swelling face								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Vaccination site pain								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hepatobiliary disorders								
All								
Normal	5	(1.8)	6	4.35	4	(1.4)	4	2.84
Impaired	0				0			
Missing	0				0			
Gallbladder disorder								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Gallbladder polyp								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Hepatic calcification								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Hepatic steatosis								
Normal	3	(1.1)	3	2.18	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypertransaminasaemia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypersensitivity								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Infections and infestations								
All								
Normal	98	(34.9)	136	98.70	96	(33.7)	138	98.14
Impaired	0				0			
Missing	6	(75.0)	11	273.88	5	(71.4)	10	284.91
Abscess limb								
Normal	1	(0.4)	1	0.73	1	(0.4)	2	1.42
Impaired	0				0			
Missing	0				0			
Acute sinusitis								
Normal	0				3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Breast abscess								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	4	(1.4)	4	2.90	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Conjunctivitis								
Normal	4	(1.4)	4	2.90	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronavirus infection								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	28	(10.0)	29	21.05	30	(10.5)	32	22.76
Impaired	0				0			
Missing	1	(12.5)	1	24.90	2	(28.6)	2	56.98
COVID-19 pneumonia								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cystitis								
Normal	3	(1.1)	3	2.18	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cystitis escherichia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Eye infection								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Fungal skin infection								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Gastric infection								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Gastroenteritis								
Normal	6	(2.1)	7	5.08	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Gastroenteritis viral								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Gastrointestinal infection								
Normal	1	(0.4)	1	0.73	2	(0.7)	3	2.13
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Genital infection fungal								
Normal	1	(0.4)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Herpes zoster								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Hordeolum								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Infected cyst								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	1	(0.4)	1	0.73	5	(1.8)	5	3.56
Impaired	0				0			
Missing	0				0			
Laryngitis								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Localised infection								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Lower respiratory tract infection								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	30	(10.7)	34	24.68	34	(11.9)	41	29.16
Impaired	0				0			
Missing	4	(50.0)	8	199.18	2	(28.6)	2	56.98
Norovirus infection								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis externa								
Normal	0				3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Periodontitis								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Pharyngitis								
Normal	4	(1.4)	4	2.90	1	(0.4)	1	0.71
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Pneumonia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection viral								
Normal	3	(1.1)	3	2.18	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Rhinitis								
Normal	2	(0.7)	2	1.45	4	(1.4)	5	3.56
Impaired	0				0			
Missing	0				0			
Severe acute respiratory syndrome								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Sinusitis								
Normal	5	(1.8)	5	3.63	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Skin infection								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tinea cruris								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Tinea pedis								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Tonsillitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Upper respiratory tract infection								
Normal	6	(2.1)	6	4.35	6	(2.1)	6	4.27
Impaired	0				0			
Missing	0				1	(14.3)	2	56.98
Urinary tract infection								
Normal	5	(1.8)	5	3.63	4	(1.4)	6	4.27
Impaired	0				0			
Missing	1	(12.5)	1	24.90	2	(28.6)	2	56.98
Vaginal infection								
Normal	1	(0.4)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Viral infection								
Normal	1	(0.4)	1	0.73	4	(1.4)	4	2.84
Impaired	0				0			
Missing	0				0			
Vulvitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Vulvovaginitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injury, poisoning and procedural complications								
All								
Normal	29	(10.3)	36	26.13	31	(10.9)	37	26.31
Impaired	0				0			
Missing	1	(12.5)	1	24.90	2	(28.6)	2	56.98
Accidental overdose								
Normal	7	(2.5)	8	5.81	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Anaemia postoperative								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Animal scratch								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Arthropod bite								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Back injury								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Burns first degree								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Clavicle fracture								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	1	(0.4)	1	0.73	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Corneal abrasion								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epicondylitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Face injury								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Fall								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Fibula fracture								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hand fracture								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Heat stroke								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Incorrect dose administered								
Normal	3	(1.1)	3	2.18	0			
Impaired	0				0			
Missing	0				0			
Joint injury								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Limb injury								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Medication error								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Muscle strain								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Nerve injury								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Prescribed overdose								
Normal	5	(1.8)	5	3.63	0			
Impaired	0				0			
Missing	0				0			
Procedural pain								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Product administration error								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Product dispensing error								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Radius fracture								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Road traffic accident								
Normal	1	(0.4)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Skin abrasion								
Normal	1	(0.4)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Skin laceration								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Tooth fracture								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination complication								
Normal	5	(1.8)	5	3.63	8	(2.8)	11	7.82
Impaired	0				0			
Missing	0				0			
Wound								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Wound dehiscence								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Wrong product administered								
Normal	0				4	(1.4)	4	2.84
Impaired	0				0			
Missing	0				0			
Investigations								
All								
Normal	14	(5.0)	15	10.89	11	(3.9)	12	8.53
Impaired	0				0			
Missing	0				2	(28.6)	3	85.47
Angiogram								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Aspartate aminotransferase increased								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Blood cholesterol increased								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Blood glucose increased								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Blood pressure increased								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Blood testosterone decreased								
Normal	1	(0.4)	1	0.73	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Blood triglycerides increased								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Blood uric acid increased								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cardiac murmur								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Electrocardiogram abnormal								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Eosinophil count increased								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	2	56.98
Haemoglobin decreased								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Heart rate increased								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Hepatic enzyme increased								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hepatitis B virus test positive								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Lipids abnormal								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Low density lipoprotein increased								
Normal	1	(0.4)	1	0.73	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Mycobacterium tuberculosis complex test positive								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Occult blood positive								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								
Normal	0				4	(1.4)	4	2.84
Impaired	0				0			
Missing	0				0			
Weight decreased								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Weight increased								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
White blood cell count decreased								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

adsl.xpt; variable(s): OTMTDURY CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL06FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
Normal	8	(2.8)	10	7.26	8	(2.8)	10	7.11
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Dehydration								
Normal	0				1	(0.4)	2	1.42
Impaired	0				0			
Missing	0				0			
Hypercholesterolaemia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hyperuricaemia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	5	(1.8)	7	5.08	3	(1.1)	4	2.84
Impaired	0				0			
Missing	0				0			
Hyponatraemia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Insulin resistance								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Obesity								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Vitamin D deficiency								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Musculoskeletal and connective tissue disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	25	(8.9)	28	20.32	38	(13.3)	60	42.67
Impaired	0				0			
Missing	2	(25.0)	3	74.69	1	(14.3)	3	85.47
Arthralgia								
Normal	5	(1.8)	5	3.63	9	(3.2)	9	6.40
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Arthritis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Back pain								
Normal	3	(1.1)	3	2.18	11	(3.9)	25	17.78
Impaired	0				0			
Missing	0				0			
Bursitis								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Chondromalacia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Groin pain								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Limb discomfort								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Limb mass								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Muscle spasms								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Muscular weakness								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal stiffness								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Myalgia								
Normal	2	(0.7)	2	1.45	7	(2.5)	8	5.69
Impaired	0				0			
Missing	0				0			
Neck pain								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Nodal osteoarthritis								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Osteoarthritis								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	2	(25.0)	2	49.80	1	(14.3)	1	28.49
Pain in extremity								
Normal	6	(2.1)	6	4.35	5	(1.8)	5	3.56
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Periarthritis								
Normal	0				3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Rheumatoid arthritis								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Synovial cyst								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Tendonitis								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Tenosynovitis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Trigger finger								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	4	(1.4)	4	2.90	2	(0.7)	3	2.13
Impaired	0				0			
Missing	0				0			
Benign neoplasm of thyroid gland								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Benign renal neoplasm								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Eye naevus								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Haemangioma of liver								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Melanocytic naevus								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Uterine leiomyoma								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Nervous system disorders								
All								
Normal	26	(9.3)	43	31.21	24	(8.4)	78	55.47
Impaired	0				0			
Missing	1	(12.5)	3	74.69	0			
Autonomic nervous system imbalance								
Normal	1	(0.4)	1	0.73	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Burning sensation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Carpal tunnel syndrome								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cervicobrachial syndrome								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Disturbance in attention								
Normal	1	(0.4)	9	6.53	0			
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	2	(0.7)	3	2.18	2	(0.7)	3	2.13
Impaired	0				0			
Missing	0				0			
Dizziness postural								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Encephalopathy								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Haemorrhage intracranial								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Headache								
Normal	12	(4.3)	16	11.61	10	(3.5)	13	9.25
Impaired	0				0			
Missing	1	(12.5)	3	74.69	0			
Hypoaesthesia								
Normal	0				1	(0.4)	1	0.71

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Hypoglycaemic seizure								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypoglycaemic unconsciousness								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypotonia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Loss of consciousness								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	2	(0.7)	3	2.18	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Neuropathy peripheral								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Post herpetic neuralgia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Sinus headache								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Somnolence								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Speech disorder								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Syncope								
Normal	1	(0.4)	1	0.73	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	1	(0.4)	1	0.73	2	(0.7)	49	34.85
Impaired	0				0			
Missing	0				0			
Psychiatric disorders								
All								
Normal	5	(1.8)	5	3.63	4	(1.4)	5	3.56
Impaired	0				0			
Missing	0				2	(28.6)	2	56.98
Anxiety								
Normal	1	(0.4)	1	0.73	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Attention deficit hyperactivity disorder								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Depressed mood								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Depression								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				1	(14.3)	1	28.49
Insomnia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Sleep disorder								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Normal	3	(1.1)	3	2.18	3	(1.1)	6	4.27
Impaired	0				0			
Missing	0				0			
Chronic kidney disease								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Diabetic nephropathy								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Hydrocalyx								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Hypertensive nephropathy								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Microalbuminuria								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Renal pain								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Reproductive system and breast disorders								
All								
Normal	3	(1.1)	3	2.18	4	(1.4)	6	4.27
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Benign prostatic hyperplasia								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Dysmenorrhoea								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Ectropion of cervix								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Fibrocystic breast disease								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Ovarian disorder								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Penile pain								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Premenstrual syndrome								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Prostatomegaly								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Respiratory, thoracic and mediastinal disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	20	(7.1)	23	16.69	21	(7.4)	29	20.62
Impaired	0				0			
Missing	1	(12.5)	3	74.69	0			
Allergic cough								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Bronchial hyperreactivity								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Cough								
Normal	2	(0.7)	3	2.18	8	(2.8)	9	6.40
Impaired	0				0			
Missing	1	(12.5)	2	49.80	0			
Dyspnoea exertional								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Epistaxis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Hiccups								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Nasal congestion								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	5	(1.8)	5	3.63	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Pleurisy								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Productive cough								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulmonary congestion								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Respiratory disorder								
Normal	4	(1.4)	4	2.90	2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Rhinitis allergic								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	2	(0.7)	2	1.45	6	(2.1)	6	4.27
Impaired	0				0			
Missing	0				0			
Sinus congestion								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Sneezing								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Throat irritation								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Upper-airway cough syndrome								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	22	(7.8)	22	15.97	24	(8.4)	32	22.76
Impaired	0				0			
Missing	2	(25.0)	2	49.80	0			
Alopecia								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angioedema								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Blister								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Chronic spontaneous urticaria								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Cold sweat								
Normal	0				5	(1.8)	9	6.40
Impaired	0				0			
Missing	0				0			
Dermal cyst								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Dermatitis								
Normal	4	(1.4)	4	2.90	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Dermatitis atopic								
Normal	0				2	(0.7)	2	1.42
Impaired	0				0			
Missing	0				0			
Dermatitis contact								
Normal	2	(0.7)	2	1.45	6	(2.1)	6	4.27
Impaired	0				0			
Missing	0				0			
Dry skin								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Erythema								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hidradenitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	24.90	0			
Hyperkeratosis								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Ingrown hair								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Lichen sclerosus								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Macule								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Rash								
Normal	3	(1.1)	3	2.18	0			
Impaired	0				0			
Missing	0				0			
Rash erythematous								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Skin irritation								
Normal	2	(0.7)	2	1.45	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Skin lesion								
Normal	1	(0.4)	1	0.73	1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			
Telangiectasia								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (main part) - main-on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urticaria								
Normal	0				3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Xeroderma								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Surgical and medical procedures								
All								
Normal	2	(0.7)	2	1.45	0			
Impaired	0				0			
Missing	0				0			
Cardiac ablation								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Skin neoplasm excision								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Vascular disorders								
All								
Normal	6	(2.1)	6	4.35	4	(1.4)	4	2.84
Impaired	0				0			
Missing	0				0			
Arteriosclerosis								
Normal	1	(0.4)	1	0.73	0			
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	5	(1.8)	5	3.63	3	(1.1)	3	2.13
Impaired	0				0			
Missing	0				0			
Varicose vein								
Normal	0				1	(0.4)	1	0.71
Impaired	0				0			
Missing	0				0			

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