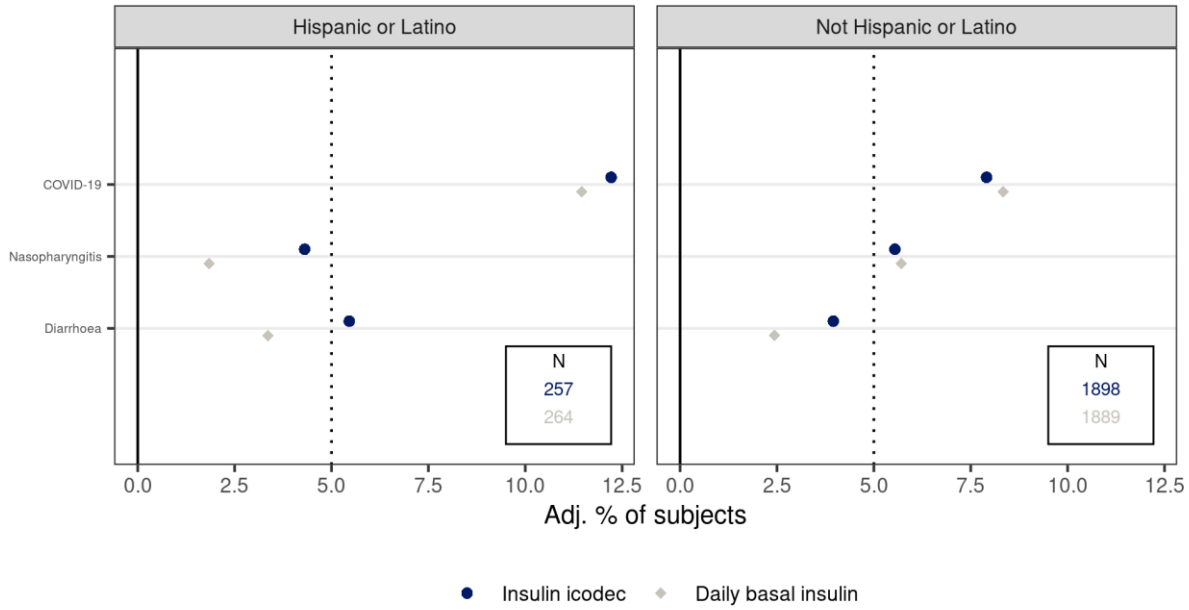
7.7.31 Adverse events by ethnicity and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

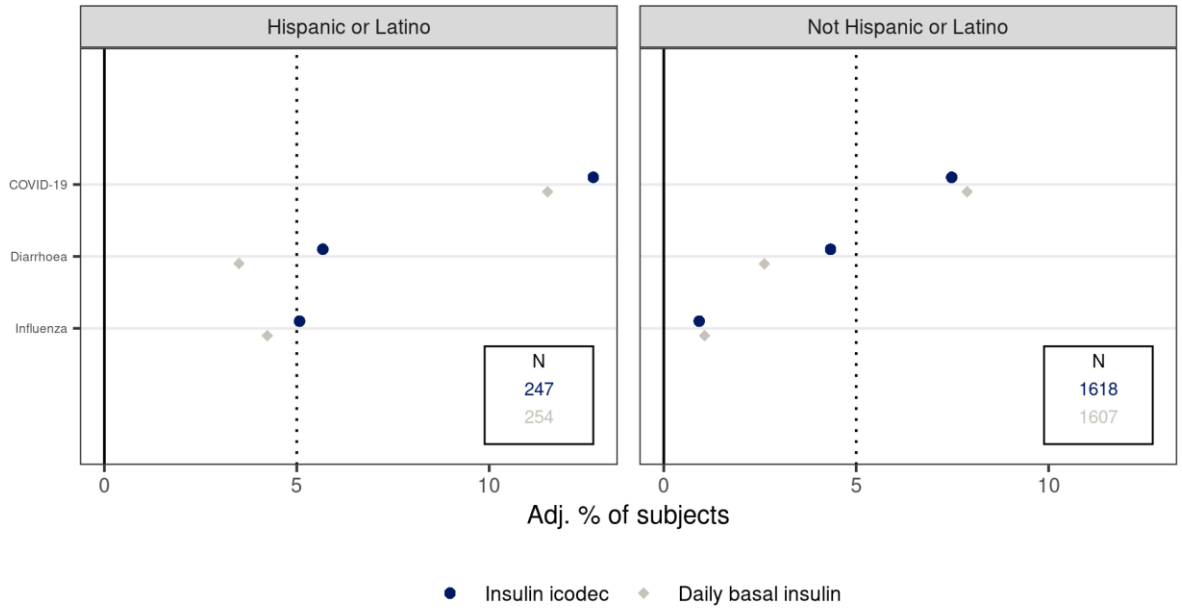


% of subjects: Percentage of subjects with one or more events, N: Number of subjects. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Subjects from France did not report ethnicity. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): ETHNIC; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD ETHNIC; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:23 - faedotgrp/faept5pctgrpethnicitydotontp3asas.png

7.7.32 Adverse events by ethnicity and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Subjects from France did not report ethnicity. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): ETHNIC; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD ETHNIC; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:29 - faedotgrp/faept5pctgrpethnicitydotontt2dsas.png

7.7.33 Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Europe	918				894			
North America	697				661			
South America	128				131			
Africa	25				25			
Asia	402				459			
PYE (years)								
Europe	760.68				732.19			
North America	545.23				535.57			
South America	82.20				85.02			
Africa	15.03				14.82			
Asia	278.09				312.98			
Events								
Europe	540	(58.9)	1713	252.19	503	(56.2)	1548	234.10
North America	447	(63.9)	1335	256.71	402	(61.0)	1187	243.50
South America	83	(65.1)	193	237.97	79	(60.0)	198	233.25
Africa	16	(64.0)	74	492.32	16	(64.0)	42	283.35
Asia	242	(60.3)	670	245.16	263	(57.4)	903	295.73
Serious								
Yes								
Europe	89	(9.6)	136	18.51	89	(10.0)	122	16.83
North America	43	(6.2)	69	12.69	47	(7.0)	79	13.52
South America	8	(6.3)	8	9.67	4	(3.0)	5	5.34
Africa	4	(16.0)	9	59.88	2	(8.0)	2	13.49
Asia	22	(5.4)	23	8.90	27	(6.0)	30	9.74
No								
Europe	517	(56.4)	1577	233.68	484	(54.0)	1426	217.27
North America	437	(62.5)	1266	244.03	387	(58.7)	1108	229.98
South America	81	(63.4)	185	228.30	79	(60.0)	193	227.91
Africa	15	(60.0)	65	432.45	16	(64.0)	40	269.86
Asia	237	(59.0)	647	236.26	257	(56.1)	873	285.99
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Severity								
Severe								
Europe	38	(4.1)	50	7.51	38	(4.3)	51	7.14
North America	36	(5.2)	50	9.08	37	(5.5)	66	10.57
South America	7	(5.5)	7	8.84	3	(2.3)	3	4.15
Africa	3	(12.0)	6	39.92	1	(4.0)	2	13.49
Asia	8	(2.0)	8	3.63	10	(2.2)	11	3.41
Moderate								
Europe	241	(26.2)	443	64.48	208	(23.3)	397	58.43
North America	176	(25.4)	339	62.34	179	(27.0)	324	63.60
South America	34	(26.7)	56	65.57	33	(25.1)	54	67.78
Africa	11	(44.0)	25	166.33	11	(44.0)	15	101.20
Asia	50	(12.3)	68	21.45	47	(10.4)	66	19.16
Mild								
Europe	436	(47.6)	1220	180.20	429	(47.9)	1100	168.53
North America	380	(54.4)	946	185.30	321	(48.7)	797	169.32
South America	69	(54.1)	130	163.56	65	(49.3)	141	161.31
Africa	12	(48.0)	43	286.08	13	(52.0)	25	168.66
Asia	216	(53.9)	594	220.08	245	(53.4)	826	273.16
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to basal insulin								
Probable								
Europe	34	(3.7)	41	6.82	21	(2.4)	33	5.29
North America	24	(3.5)	30	6.03	22	(3.3)	49	8.71
South America	9	(7.0)	14	18.21	10	(7.7)	10	12.68
Africa	2	(8.0)	2	13.31	0			
Asia	13	(3.3)	33	11.99	23	(5.0)	41	11.49
Possible								
Europe	42	(4.6)	57	9.47	33	(3.7)	42	6.65
North America	44	(6.2)	58	12.02	36	(5.4)	48	9.51
South America	3	(2.4)	3	3.47	2	(1.5)	2	2.60
Africa	2	(8.0)	7	46.57	2	(8.0)	2	13.49
Asia	34	(8.5)	54	20.16	32	(6.9)	84	29.91
Unlikely								
Europe	526	(57.3)	1607	234.53	492	(55.0)	1471	221.85
North America	433	(61.9)	1244	238.07	389	(59.1)	1088	225.00
South America	78	(61.2)	176	216.29	76	(57.7)	186	217.96
Africa	15	(60.0)	65	432.45	16	(64.0)	40	269.86
Asia	224	(55.8)	582	212.55	253	(55.2)	776	253.63
Missing								
Europe	4	(0.4)	8	1.37	2	(0.2)	2	0.31
North America	3	(0.4)	3	0.59	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	2	(0.4)	2	0.71

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to technical complaint for basal insulin								
Yes								
Europe	2	(0.2)	2	0.39	1	(0.1)	1	0.19
North America	4	(0.5)	4	0.93	2	(0.3)	2	0.55
South America	3	(2.3)	3	4.05	2	(1.5)	3	4.15
Africa	0				1	(4.0)	1	6.75
Asia	2	(0.5)	2	0.82	1	(0.2)	1	0.40
No								
Europe	539	(58.8)	1702	250.24	501	(56.0)	1544	233.41
North America	445	(63.7)	1328	255.20	400	(60.7)	1183	242.67
South America	83	(65.1)	190	233.92	79	(60.0)	195	229.09
Africa	16	(64.0)	74	492.32	16	(64.0)	41	276.60
Asia	242	(60.3)	667	243.88	262	(57.2)	899	294.22
NA								
Europe	1	(0.1)	1	0.18	1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Missing								
Europe	4	(0.4)	8	1.37	2	(0.2)	2	0.31
North America	3	(0.4)	3	0.59	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	3	(0.6)	3	1.11

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Outcome								
Fatal								
Europe	9	(1.0)	13	2.08	6	(0.7)	7	0.91
North America	5	(0.7)	5	0.99	5	(0.7)	5	0.83
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	3	0.81
Not recovered/not resolved								
Europe	212	(23.1)	426	58.93	217	(24.3)	426	61.64
North America	217	(31.3)	402	75.10	177	(26.6)	332	65.09
South America	30	(23.2)	36	47.25	28	(21.5)	41	51.68
Africa	8	(32.0)	19	126.41	9	(36.0)	18	121.44
Asia	122	(30.5)	204	78.16	139	(30.3)	225	73.39
Recovered/resolved with sequelae								
Europe	5	(0.5)	5	0.53	8	(0.9)	9	1.17
North America	1	(0.2)	1	0.15	8	(1.2)	9	2.13
South America	4	(3.2)	4	4.30	0			
Africa	0				0			
Asia	0				0			
Recovering/resolving								
Europe	31	(3.4)	55	9.55	21	(2.3)	26	4.35
North America	40	(5.7)	49	9.64	41	(6.3)	54	11.75
South America	10	(8.0)	15	14.90	13	(9.6)	13	12.49
Africa	2	(8.0)	2	13.31	1	(4.0)	1	6.75
Asia	13	(3.2)	15	5.40	16	(3.6)	17	6.02
Recovered/resolved								
Europe	486	(53.0)	1214	181.10	426	(47.5)	1079	165.91
North America	367	(52.4)	877	170.68	330	(50.1)	786	163.57
South America	72	(56.4)	138	171.52	65	(49.3)	144	169.08
Africa	14	(56.0)	53	352.61	12	(48.0)	23	155.17
Asia	183	(45.4)	451	161.59	206	(44.9)	658	215.52
Unknown								
Europe	0				1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.7.34 Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Europe	782				755			
North America	591				576			
South America	128				131			
Africa	25				25			
Asia	354				391			
PYE (years)								
Europe	693.26				663.77			
North America	494.44				493.99			
South America	82.20				85.02			
Africa	15.03				14.82			
Asia	254.00				278.87			
Events								
Europe	443	(56.6)	1424	220.57	412	(54.5)	1266	202.21
North America	384	(64.7)	1193	253.01	347	(60.4)	1065	235.40
South America	83	(65.1)	193	237.97	79	(60.0)	198	233.25
Africa	16	(64.0)	74	492.32	16	(64.0)	42	283.35
Asia	213	(60.2)	594	234.48	219	(56.3)	688	244.96
Serious								
Yes								
Europe	82	(10.4)	126	19.17	85	(11.3)	116	18.28
North America	41	(6.9)	66	13.79	47	(8.2)	79	15.71
South America	8	(6.3)	8	9.67	4	(3.0)	5	5.34
Africa	4	(16.0)	9	59.88	2	(8.0)	2	13.49
Asia	20	(5.6)	21	8.99	24	(6.2)	27	9.89
No								
Europe	422	(54.0)	1298	201.41	394	(52.1)	1150	183.93
North America	375	(63.2)	1127	239.22	332	(57.8)	986	219.69
South America	81	(63.4)	185	228.30	79	(60.0)	193	227.91
Africa	15	(60.0)	65	432.45	16	(64.0)	40	269.86
Asia	209	(59.1)	573	225.49	215	(55.3)	661	235.08
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Severity								
Severe								
Europe	34	(4.3)	45	7.52	35	(4.7)	47	7.37
North America	33	(5.6)	47	9.59	36	(6.2)	65	11.90
South America	7	(5.5)	7	8.84	3	(2.3)	3	4.15
Africa	3	(12.0)	6	39.92	1	(4.0)	2	13.49
Asia	6	(1.7)	6	2.92	10	(2.5)	11	3.92
Moderate								
Europe	209	(26.7)	380	59.29	177	(23.5)	336	52.93
North America	158	(26.7)	313	64.15	163	(28.4)	300	64.56
South America	34	(26.7)	56	65.57	33	(25.1)	54	67.78
Africa	11	(44.0)	25	166.33	11	(44.0)	15	101.20
Asia	49	(13.8)	67	24.07	43	(11.1)	62	20.29
Mild								
Europe	348	(44.5)	999	153.76	347	(45.9)	883	141.90
North America	326	(55.0)	833	179.27	275	(47.8)	700	158.94
South America	69	(54.1)	130	163.56	65	(49.3)	141	161.31
Africa	12	(48.0)	43	286.08	13	(52.0)	25	168.66
Asia	189	(53.5)	521	207.49	203	(52.2)	615	220.75
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to basal insulin								
Probable								
Europe	22	(2.8)	26	4.05	18	(2.4)	30	5.46
North America	21	(3.6)	27	6.05	20	(3.5)	47	9.34
South America	9	(7.0)	14	18.21	10	(7.7)	10	12.68
Africa	2	(8.0)	2	13.31	0			
Asia	11	(3.1)	31	12.55	21	(5.4)	38	11.90
Possible								
Europe	34	(4.4)	48	8.78	26	(3.4)	34	5.75
North America	37	(6.2)	50	11.42	35	(6.0)	47	10.66
South America	3	(2.4)	3	3.47	2	(1.5)	2	2.60
Africa	2	(8.0)	7	46.57	2	(8.0)	2	13.49
Asia	27	(7.5)	45	17.55	23	(6.0)	52	20.21
Unlikely								
Europe	435	(55.6)	1342	206.12	401	(53.1)	1200	190.64
North America	372	(62.7)	1113	234.86	334	(58.2)	969	215.07
South America	78	(61.2)	176	216.29	76	(57.7)	186	217.96
Africa	15	(60.0)	65	432.45	16	(64.0)	40	269.86
Asia	198	(56.1)	517	203.86	210	(53.9)	596	212.04
Missing								
Europe	4	(0.5)	8	1.62	2	(0.3)	2	0.37
North America	3	(0.5)	3	0.68	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	2	(0.5)	2	0.82

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to technical complaint for basal insulin								
Yes								
Europe	2	(0.3)	2	0.46	1	(0.1)	1	0.22
North America	4	(0.6)	4	1.08	2	(0.4)	2	0.64
South America	3	(2.3)	3	4.05	2	(1.5)	3	4.15
Africa	0				1	(4.0)	1	6.75
Asia	2	(0.5)	2	0.95	1	(0.3)	1	0.47
No								
Europe	442	(56.5)	1413	218.28	410	(54.3)	1262	201.39
North America	382	(64.3)	1186	251.25	345	(60.1)	1061	234.43
South America	83	(65.1)	190	233.92	79	(60.0)	195	229.09
Africa	16	(64.0)	74	492.32	16	(64.0)	41	276.60
Asia	213	(60.2)	591	233.01	218	(56.0)	684	243.21
NA								
Europe	1	(0.1)	1	0.21	1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Missing								
Europe	4	(0.5)	8	1.62	2	(0.3)	2	0.37
North America	3	(0.5)	3	0.68	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	3	(0.7)	3	1.28

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Outcome								
Fatal								
Europe	9	(1.2)	13	2.45	6	(0.8)	7	1.08
North America	4	(0.7)	4	0.83	5	(0.8)	5	0.96
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	3	0.93
Not recovered/not resolved								
Europe	176	(22.5)	374	55.66	181	(24.0)	357	54.62
North America	188	(31.9)	359	73.55	155	(26.7)	299	62.77
South America	30	(23.2)	36	47.25	28	(21.5)	41	51.68
Africa	8	(32.0)	19	126.41	9	(36.0)	18	121.44
Asia	101	(28.5)	165	65.46	114	(29.4)	183	65.84
Recovered/resolved with sequelae								
Europe	5	(0.6)	5	0.63	8	(1.1)	9	1.38
North America	1	(0.2)	1	0.18	5	(0.9)	6	1.30
South America	4	(3.2)	4	4.30	0			
Africa	0				0			
Asia	0				0			
Recovering/resolving								
Europe	27	(3.5)	51	10.20	20	(2.6)	25	4.87
North America	38	(6.3)	47	10.57	37	(6.5)	47	10.92
South America	10	(8.0)	15	14.90	13	(9.6)	13	12.49
Africa	2	(8.0)	2	13.31	1	(4.0)	1	6.75
Asia	13	(3.7)	15	6.22	16	(4.1)	17	6.93
Recovered/resolved								
Europe	394	(50.3)	981	151.63	345	(45.6)	867	140.13
North America	315	(52.9)	781	167.71	285	(49.7)	707	159.28
South America	72	(56.4)	138	171.52	65	(49.3)	144	169.08
Africa	14	(56.0)	53	352.61	12	(48.0)	23	155.17
Asia	167	(47.3)	414	162.81	171	(44.0)	485	171.26
Unknown								
Europe	0				1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Missing								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.7.35 Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Europe	918				894			
North America	697				661			
South America	128				131			
Africa	25				25			
Asia	402				459			
PYE (years)								
Europe	760.68				732.19			
North America	545.23				535.57			
South America	82.20				85.02			
Africa	15.03				14.82			
Asia	278.09				312.98			
Events								
Europe	540	(58.9)	1713	252.19	503	(56.2)	1548	234.10
North America	447	(63.9)	1335	256.71	402	(61.0)	1187	243.50
South America	83	(65.1)	193	237.97	79	(60.0)	198	233.25
Africa	16	(64.0)	74	492.32	16	(64.0)	42	283.35
Asia	242	(60.3)	670	245.16	263	(57.4)	903	295.73
Infections and infestations								
All								
Europe	305	(33.3)	445	67.98	281	(31.4)	437	66.24
North America	218	(31.0)	307	60.83	203	(30.8)	273	58.97
South America	42	(32.7)	60	75.84	43	(32.4)	66	74.68
Africa	9	(36.0)	14	93.14	5	(20.0)	6	40.48
Asia	74	(18.4)	94	33.96	92	(20.2)	123	38.07
COVID-19								
Europe	93	(10.2)	94	14.31	105	(11.8)	110	16.18
North America	68	(9.9)	71	13.66	65	(9.8)	67	13.61
South America	16	(12.4)	16	20.89	14	(10.4)	14	14.50
Africa	0				2	(8.0)	2	13.49
Asia	4	(1.0)	4	1.52	6	(1.3)	6	1.84
Nasopharyngitis								
Europe	72	(7.9)	91	15.50	64	(7.1)	78	13.72
North America	18	(2.5)	20	4.48	20	(3.1)	22	5.61
South America	4	(3.1)	4	5.32	2	(1.5)	2	2.60
Africa	0				0			
Asia	23	(5.8)	26	9.39	29	(6.3)	33	9.94

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Upper respiratory tract infection								
Europe	27	(2.9)	34	3.85	14	(1.6)	15	1.94
North America	29	(4.1)	34	6.82	26	(4.0)	28	6.20
South America	0				0			
Africa	2	(8.0)	3	19.96	1	(4.0)	1	6.75
Asia	10	(2.4)	10	3.63	11	(2.5)	12	4.27
Urinary tract infection								
Europe	16	(1.7)	16	2.21	14	(1.6)	17	2.74
North America	20	(2.9)	23	4.98	26	(3.9)	28	5.22
South America	3	(2.4)	3	3.47	6	(4.5)	6	6.18
Africa	1	(4.0)	1	6.65	0			
Asia	3	(0.7)	3	1.07	4	(0.9)	5	1.67
Influenza								
Europe	14	(1.6)	14	2.34	15	(1.7)	17	2.94
North America	4	(0.6)	4	0.76	6	(1.0)	6	1.62
South America	11	(8.5)	14	18.52	11	(8.4)	12	15.66
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Bronchitis								
Europe	14	(1.5)	14	2.13	5	(0.6)	5	0.69
North America	11	(1.5)	12	2.31	8	(1.2)	8	1.75
South America	0				0			
Africa	0				0			
Asia	5	(1.2)	5	2.05	6	(1.3)	6	1.87
Gastroenteritis								
Europe	13	(1.4)	14	2.51	4	(0.4)	5	0.84
North America	10	(1.4)	10	2.12	6	(1.0)	6	1.62
South America	2	(1.5)	2	2.64	3	(2.2)	3	2.73
Africa	3	(12.0)	3	19.96	1	(4.0)	1	6.75
Asia	4	(1.0)	4	1.62	4	(0.9)	4	1.24
COVID-19 pneumonia								
Europe	13	(1.4)	13	1.93	6	(0.7)	6	0.74
North America	2	(0.3)	2	0.38	4	(0.6)	4	0.88
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Respiratory tract infection viral								
Europe	12	(1.4)	13	2.43	10	(1.1)	11	1.92
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pharyngitis								
Europe	11	(1.2)	12	1.85	9	(1.0)	10	1.31
North America	1	(0.2)	2	0.31	0			
South America	6	(4.9)	6	6.00	7	(5.2)	8	8.57
Africa	0				0			
Asia	3	(0.8)	3	1.20	2	(0.5)	3	1.21
Respiratory tract infection								
Europe	8	(0.9)	8	1.26	6	(0.7)	6	0.81
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rhinitis								
Europe	8	(0.9)	8	1.10	7	(0.8)	8	1.35
North America	0				1	(0.2)	3	0.85
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.60
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Pneumonia								
Europe	7	(0.8)	7	0.97	4	(0.4)	4	0.51
North America	6	(0.8)	6	1.19	1	(0.1)	1	0.26
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.41
Cystitis								
Europe	6	(0.7)	6	1.07	9	(1.0)	10	1.41
North America	1	(0.1)	1	0.25	0			
South America	3	(2.3)	3	4.05	1	(0.8)	1	1.43
Africa	0				0			
Asia	5	(1.2)	6	1.70	7	(1.5)	8	2.23
Conjunctivitis								
Europe	5	(0.5)	5	0.88	2	(0.2)	2	0.28
North America	3	(0.4)	3	0.53	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	1.50	4	(0.9)	4	1.26
Lower respiratory tract infection								
Europe	5	(0.5)	5	0.66	2	(0.2)	4	0.57
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tooth infection								
Europe	4	(0.4)	4	0.51	4	(0.5)	4	0.69
North America	5	(0.7)	7	1.42	3	(0.5)	3	0.72
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Gastroenteritis viral								
Europe	3	(0.3)	3	0.54	2	(0.2)	2	0.44
North America	3	(0.5)	3	0.46	3	(0.4)	3	0.43
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Tooth abscess								
Europe	3	(0.3)	3	0.54	2	(0.2)	2	0.22
North America	6	(0.8)	6	1.28	5	(0.8)	6	1.32
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal infection								
Europe	3	(0.3)	3	0.59	5	(0.6)	7	1.10
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Genital infection								
Europe	3	(0.3)	3	0.39	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Tonsillitis								
Europe	3	(0.3)	3	0.43	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	1	(0.2)	1	0.35
Erysipelas								
Europe	3	(0.3)	3	0.40	0			
North America	0				1	(0.1)	1	0.14
South America	0				1	(0.8)	2	2.60
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sinusitis								
Europe	3	(0.3)	3	0.44	6	(0.7)	8	1.00
North America	16	(2.2)	18	3.67	12	(1.9)	12	2.87
South America	0				1	(0.7)	2	1.43
Africa	0				0			
Asia	0				0			
Viral infection								
Europe	3	(0.3)	3	0.40	10	(1.1)	13	1.84
North America	4	(0.6)	4	0.81	3	(0.5)	3	0.63
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronavirus infection								
Europe	3	(0.3)	3	0.31	5	(0.6)	7	1.04
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Periodontitis								
Europe	2	(0.2)	2	0.43	2	(0.2)	2	0.30
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	3	0.90	5	(1.1)	5	1.65
Sepsis								
Europe	2	(0.2)	2	0.39	0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Abscess								
Europe	2	(0.2)	2	0.31	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteomyelitis								
Europe	2	(0.2)	2	0.31	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gingivitis								
Europe	2	(0.2)	3	0.44	2	(0.2)	2	0.34
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				3	(0.7)	3	1.16
Hordeolum								
Europe	2	(0.2)	2	0.33	0			
North America	1	(0.2)	1	0.15	4	(0.6)	4	1.00
South America	0				0			
Africa	0				0			
Asia	0				0			
Otitis media								
Europe	2	(0.2)	2	0.28	1	(0.1)	1	0.12
North America	2	(0.3)	2	0.48	3	(0.5)	3	0.76
South America	0				1	(0.8)	1	1.43
Africa	2	(8.0)	2	13.31	0			
Asia	1	(0.2)	1	0.25	0			
Acarodermatitis								
Europe	2	(0.2)	2	0.20	3	(0.3)	3	0.32
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Fungal infection								
Europe	2	(0.2)	2	0.21	0			
North America	4	(0.6)	5	0.99	2	(0.3)	2	0.44
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Herpes zoster								
Europe	2	(0.2)	2	0.21	7	(0.8)	7	0.98
North America	5	(0.7)	5	0.96	7	(1.1)	8	1.50
South America	1	(0.8)	1	0.83	0			
Africa	0				1	(4.0)	1	6.75
Asia	3	(0.7)	3	0.90	2	(0.4)	2	0.58
Laryngitis								
Europe	2	(0.2)	2	0.21	4	(0.4)	4	0.63
North America	1	(0.2)	1	0.15	0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vulvovaginal candidiasis								
Europe	2	(0.2)	3	0.32	3	(0.3)	3	0.35
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.2)	1	0.23
Pneumonia viral								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary tuberculoma								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral tracheitis								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Breast abscess								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.12
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Fungal skin infection								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.18
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Norovirus infection								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tinea cruris								
Europe	1	(0.1)	1	0.23	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea pedis								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.22
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Vulvovaginitis								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Onychomycosis								
Europe	1	(0.1)	1	0.18	2	(0.2)	2	0.21
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulpitis dental								
Europe	1	(0.1)	1	0.18	1	(0.1)	1	0.18
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				2	(0.4)	2	0.58
Clostridium difficile colitis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear infection fungal								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nail infection								
Europe	1	(0.1)	2	0.20	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peritonsillar abscess								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Vaginal infection								
Europe	1	(0.1)	1	0.10	2	(0.2)	2	0.22
North America	3	(0.4)	4	0.92	1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.82	0			
Asymptomatic COVID-19								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.29
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Balanitis candida								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Candida infection								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Cellulitis								
Europe	1	(0.1)	1	0.11	0			
North America	3	(0.4)	3	0.52	7	(1.1)	8	1.70
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chlamydial infection								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic tonsillitis								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Ear infection								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	2	(0.3)	2	0.37	4	(0.6)	4	0.83
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Helicobacter gastritis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Herpes simplex								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Herpes virus infection								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Infected bite								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Laryngopharyngitis								
Europe	1	(0.1)	1	0.11	1	(0.1)	2	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oropharyngeal candidiasis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Otitis media chronic								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea infection								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Tracheitis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urethritis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Abdominal abscess								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Abscess limb								
Europe	0				2	(0.2)	3	0.64
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Acute sinusitis								
Europe	0				2	(0.2)	2	0.44
North America	4	(0.6)	4	0.61	3	(0.5)	3	0.62
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Anal abscess								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Appendicitis								
Europe	0				1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bacteraemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Bacterial infection								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Bartholinitis								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Body tinea								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Breast cellulitis								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Campylobacter gastroenteritis								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholecystitis infective								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Chronic hepatitis C								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Chronic sinusitis								
Europe	0				2	(0.2)	2	0.23
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Clostridium difficile infection								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cystitis escherichia								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dermatophytosis of nail								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.23
Diabetic foot infection								
Europe	0				0			
North America	1	(0.1)	1	0.23	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Diverticulitis								
Europe	0				3	(0.3)	3	0.34
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Empyema								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Endophthalmitis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Enteritis infectious								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Epididymitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Escherichia bacteraemia								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Escherichia urinary tract infection								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye infection								
Europe	0				1	(0.1)	1	0.18
North America	1	(0.1)	1	0.27	2	(0.3)	2	0.58
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye infection bacterial								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Folliculitis								
Europe	0				1	(0.1)	1	0.20
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Fungal balanitis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Furuncle								
Europe	0				1	(0.1)	1	0.11
North America	0				1	(0.1)	1	0.15
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	1	(0.2)	2	0.50	0			
Gangrene								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastric infection								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastroenteritis norovirus								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Genital candidiasis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Genital infection fungal								
Europe	0				2	(0.2)	2	0.22
North America	2	(0.3)	3	0.70	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Giardiasis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Helicobacter infection								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	1	(0.2)	1	0.23
Herpes dermatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Herpes zoster infection neurological								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Infected cyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Infected dermal cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Infective iritis								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site abscess								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Kidney infection								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Labyrinthitis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Localised infection								
Europe	0				2	(0.2)	2	0.33
North America	2	(0.3)	2	0.38	1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Lyme disease								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mastitis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oophoritis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral candidiasis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Oral herpes								
Europe	0				0			
North America	2	(0.3)	3	0.71	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Otitis externa								
Europe	0				2	(0.2)	2	0.22
North America	1	(0.2)	1	0.15	3	(0.5)	3	0.81
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Otitis media acute								
Europe	0				2	(0.2)	2	0.22
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Paraspinal abscess								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Paronychia								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	2	0.81
Parotitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Peri-implantitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pericoronitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Pharyngotonsillitis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.36	2	(1.4)	3	2.15
Africa	0				0			
Asia	0				0			
Post procedural infection								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Post-acute COVID-19 syndrome								
Europe	0				0			
North America	1	(0.2)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Postoperative wound infection								
Europe	0				0			
North America	1	(0.1)	1	0.25	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Purulence								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Pustule								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pyelonephritis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Respiratory syncytial virus infection								
Europe	0				0			
North America	3	(0.4)	3	0.53	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rotavirus infection								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Salpingitis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Severe acute respiratory syndrome								
Europe	0				0			
North America	1	(0.1)	1	0.27	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinusitis bacterial								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin bacterial infection								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Skin candida								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin infection								
Europe	0				2	(0.2)	2	0.41
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Soft tissue infection								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Subcutaneous abscess								
Europe	0				0			
North America	2	(0.3)	2	0.37	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	2	0.45
Suspected COVID-19								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sweat gland infection								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea versicolour								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Urosepsis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Varicella								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Varicella zoster virus infection								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral pharyngitis								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral rhinitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral upper respiratory tract infection								
Europe	0				2	(0.2)	2	0.23
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Vulvitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	1.00	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vulvovaginal mycotic infection								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	0				0			
Wound infection								
Europe	0				0			
North America	3	(0.4)	3	0.62	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal disorders								
All								
Europe	116	(12.6)	185	26.24	86	(9.6)	123	18.61
North America	93	(13.4)	129	24.10	80	(12.1)	107	21.84
South America	10	(7.9)	12	14.41	15	(11.5)	22	27.25
Africa	5	(20.0)	10	66.53	3	(12.0)	3	20.24
Asia	53	(13.1)	82	28.75	61	(13.4)	88	28.31
Diarrhoea								
Europe	29	(3.1)	38	5.05	18	(2.0)	18	2.60
North America	34	(4.8)	40	7.59	19	(2.9)	20	4.46
South America	6	(4.8)	6	6.45	5	(3.9)	5	6.63
Africa	3	(12.0)	3	19.96	2	(8.0)	2	13.49
Asia	17	(4.1)	21	7.52	11	(2.4)	12	3.72
Nausea								
Europe	12	(1.3)	13	1.86	13	(1.5)	14	2.32
North America	17	(2.5)	17	3.19	16	(2.5)	17	3.56
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	11	(2.7)	11	3.62	5	(1.0)	5	1.76
Abdominal pain upper								
Europe	11	(1.2)	13	1.92	8	(0.9)	9	1.17
North America	3	(0.5)	3	0.56	4	(0.6)	4	0.87
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	4	(0.8)	4	1.19
Vomiting								
Europe	10	(1.1)	11	2.08	10	(1.1)	12	1.88
North America	14	(2.0)	19	4.00	6	(0.9)	6	1.31
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.30
Africa	2	(8.0)	2	13.31	0			
Asia	4	(1.0)	6	2.13	4	(0.8)	5	1.42

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Abdominal pain								
Europe	10	(1.1)	10	1.54	5	(0.6)	5	0.78
North America	6	(0.9)	6	0.98	10	(1.5)	11	2.15
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.43
Africa	0				0			
Asia	0				2	(0.5)	2	0.63
Toothache								
Europe	9	(1.0)	9	1.19	6	(0.7)	10	1.99
North America	1	(0.1)	1	0.23	3	(0.5)	3	0.72
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	5	(1.2)	5	1.45	3	(0.7)	4	1.62
Dental caries								
Europe	7	(0.8)	8	0.94	3	(0.3)	3	0.32
North America	1	(0.2)	2	0.31	2	(0.3)	2	0.44
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	0.99	5	(1.1)	5	1.92
Gastrooesophageal reflux disease								
Europe	7	(0.7)	7	0.82	5	(0.6)	5	0.68
North America	4	(0.6)	4	0.69	2	(0.3)	2	0.42
South America	0				3	(2.3)	3	3.32
Africa	0				0			
Asia	3	(0.8)	3	1.41	5	(1.1)	5	1.62
Chronic gastritis								
Europe	5	(0.6)	5	0.72	2	(0.2)	2	0.29
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	3	(0.8)	3	1.25	4	(0.8)	4	1.22
Constipation								
Europe	5	(0.6)	8	1.44	3	(0.3)	3	0.48
North America	8	(1.2)	8	1.30	4	(0.6)	4	0.58
South America	1	(0.8)	1	1.32	3	(2.3)	3	3.91
Africa	0				0			
Asia	3	(0.8)	3	1.16	6	(1.4)	6	2.07
Gastritis								
Europe	5	(0.5)	5	0.68	3	(0.3)	3	0.40
North America	0				3	(0.4)	3	0.42
South America	0				1	(0.8)	1	1.30
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	2	(0.5)	2	0.96	1	(0.2)	1	0.41
Dyspepsia								
Europe	4	(0.4)	4	0.69	2	(0.2)	2	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	2	(0.3)	2	0.30	3	(0.4)	3	0.42
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.5)	2	0.87	3	(0.6)	3	1.15
Flatulence								
Europe	4	(0.4)	4	0.58	0			
North America	0				2	(0.3)	2	0.52
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemorrhoids								
Europe	4	(0.4)	4	0.42	2	(0.2)	2	0.31
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.28
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.39
Abdominal distension								
Europe	3	(0.3)	3	0.44	1	(0.1)	1	0.22
North America	4	(0.6)	4	0.71	4	(0.6)	4	0.88
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Diverticulum intestinal								
Europe	3	(0.3)	3	0.31	1	(0.1)	1	0.11
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Large intestine polyp								
Europe	3	(0.3)	3	0.31	1	(0.1)	1	0.11
North America	1	(0.1)	1	0.22	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				3	(0.6)	4	1.03
Hypoaesthesia oral								
Europe	2	(0.2)	4	0.71	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Abdominal pain lower								
Europe	2	(0.2)	2	0.36	0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.23
Aphthous ulcer								
Europe	2	(0.2)	2	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rectal polyp								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.11
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Enterocolitis								
Europe	2	(0.2)	3	0.32	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Pancreatitis chronic								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Abdominal discomfort								
Europe	1	(0.1)	1	0.23	0			
North America	0				3	(0.5)	3	0.63
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	3	0.90	3	(0.7)	4	1.44
Anal fissure								
Europe	1	(0.1)	1	0.23	0			
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Impaired gastric emptying								
Europe	1	(0.1)	2	0.45	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatic failure								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.23	0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral pain								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vomiting projectile								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gingival bleeding								
Europe	1	(0.1)	1	0.18	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic gastropathy								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophilic oesophagitis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eructation								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal haemorrhage								
Europe	1	(0.1)	1	0.10	2	(0.2)	2	0.28
North America	0				0			
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Hiatus hernia								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.22
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Inguinal hernia								
Europe	1	(0.1)	1	0.10	1	(0.1)	2	0.23
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lip swelling								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Umbilical hernia								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.12
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Colitis								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Dry mouth								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Food poisoning								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	4	(0.6)	4	0.77	3	(0.5)	4	1.12
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Frequent bowel movements								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Loose tooth								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatitis								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tooth disorder								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Abdominal wall disorder								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acid peptic disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.45
Anal pruritus								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Colitis ischaemic								
Europe	0				0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Colitis microscopic								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Crohn's disease								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diverticulum								
Europe	0				1	(0.1)	1	0.19
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.2)	1	0.23
Duodenitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Enteritis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Epigastric discomfort								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Faeces pale								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Faeces soft								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Gastric dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Gastric disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Gastric dysplasia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Gastric mucosal hypertrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Gastric polyps								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.66	4	(0.8)	4	1.35
Gastric ulcer								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastritis erosive								
Europe	0				1	(0.1)	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Gastrointestinal angiodysplasia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Gastrointestinal disorder								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal inflammation								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal sounds abnormal								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gingival disorder								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Gingival recession								
Europe	0				1	(0.1)	2	0.44
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematochezia								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Haemorrhoidal haemorrhage								
Europe	0				1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperaesthesia teeth								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Hyperchlorhydria								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Ileus								
Europe	0				1	(0.1)	1	0.11
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Intestinal dilatation								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intra-abdominal haematoma								
Europe	0				0			
North America	1	(0.1)	1	0.22	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Irritable bowel syndrome								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lumbar hernia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Melaena								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Mesenteric panniculitis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Noninfective gingivitis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Odynophagia								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Oesophageal pain								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Oesophagitis								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Oral discomfort								
Europe	0				0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Pancreatic duct dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Pancreatic pseudocyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatitis acute								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peptic ulcer								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Periodontal disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	2	(0.4)	2	0.76
Periodontal inflammation								
Europe	0				1	(0.1)	2	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pneumatosis intestinalis								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Proctalgia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Rectal prolapse								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Small intestinal obstruction								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Stomatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.45
Tongue rough								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Tooth impacted								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.41
Ulcerative gastritis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper gastrointestinal haemorrhage								
Europe	0				0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Musculoskeletal and connective tissue disorders								
All								
Europe	110	(11.9)	167	23.19	115	(12.9)	180	28.06
North America	93	(13.4)	138	25.55	96	(14.5)	131	26.59
South America	14	(10.9)	23	27.01	11	(8.4)	11	13.52
Africa	5	(20.0)	6	39.92	5	(20.0)	6	40.48
Asia	51	(12.7)	66	23.59	57	(12.4)	73	24.04
Back pain								
Europe	31	(3.4)	34	4.81	30	(3.4)	46	8.15
North America	16	(2.3)	17	3.15	27	(4.2)	28	6.48
South America	2	(1.5)	2	2.64	2	(1.5)	2	2.60
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	15	(3.6)	15	4.69	12	(2.7)	12	3.89
Arthralgia								
Europe	17	(1.8)	19	2.71	23	(2.6)	27	4.28
North America	22	(3.1)	26	5.28	18	(2.7)	20	4.10
South America	2	(1.6)	4	4.30	1	(0.8)	1	1.30
Africa	0				2	(8.0)	2	13.49
Asia	10	(2.5)	10	2.89	13	(2.8)	13	4.44
Muscle spasms								
Europe	14	(1.5)	14	2.18	2	(0.2)	2	0.23
North America	6	(0.9)	6	0.99	3	(0.5)	3	0.58
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	4	(1.0)	6	2.68	4	(0.9)	4	1.21
Osteoarthritis								
Europe	12	(1.3)	13	1.90	17	(1.9)	19	2.49
North America	7	(1.0)	7	1.34	6	(0.9)	7	1.79
South America	4	(3.2)	5	5.17	2	(1.5)	2	2.02
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.40
Pain in extremity								
Europe	11	(1.2)	12	1.64	12	(1.3)	14	2.27
North America	20	(2.9)	21	3.73	16	(2.4)	19	3.97
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.73
Africa	1	(4.0)	1	6.65	0			
Asia	4	(1.0)	4	1.59	7	(1.5)	8	2.99
Neck pain								
Europe	10	(1.1)	10	1.36	4	(0.5)	4	0.46

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	3	(0.4)	3	0.68	2	(0.3)	2	0.44
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.5)	2	0.66	2	(0.5)	2	0.63
Myalgia								
Europe	5	(0.5)	5	0.87	4	(0.4)	4	0.83
North America	6	(0.9)	6	0.99	5	(0.7)	5	0.92
South America	3	(2.3)	3	4.00	1	(0.8)	1	1.43
Africa	0				0			
Asia	2	(0.5)	2	1.00	6	(1.2)	7	2.69
Tendonitis								
Europe	5	(0.5)	7	1.03	3	(0.3)	3	0.52
North America	3	(0.5)	3	0.46	2	(0.3)	2	0.44
South America	0				0			
Africa	0				0			
Asia	0				0			
Periarthritis								
Europe	3	(0.3)	3	0.42	3	(0.3)	3	0.45
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.48
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	1.20	4	(0.9)	4	1.24
Osteochondrosis								
Europe	2	(0.2)	2	0.30	4	(0.4)	4	0.57
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Back disorder								
Europe	2	(0.2)	2	0.31	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Musculoskeletal pain								
Europe	2	(0.2)	2	0.29	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc disorder								
Europe	2	(0.2)	2	0.29	2	(0.2)	2	0.30
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Chondropathy								
Europe	2	(0.2)	2	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc protrusion								
Europe	2	(0.2)	6	0.62	1	(0.1)	2	0.23
North America	3	(0.5)	3	0.46	2	(0.3)	2	0.29
South America	0				1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.5)	2	0.66	2	(0.5)	2	0.81
Spinal osteoarthritis								
Europe	2	(0.2)	2	0.21	2	(0.2)	2	0.22
North America	3	(0.4)	3	0.53	3	(0.4)	4	0.57
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Fibromyalgia								
Europe	2	(0.2)	2	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Musculoskeletal chest pain								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Rotator cuff syndrome								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.11
North America	1	(0.1)	1	0.23	3	(0.4)	3	0.42
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.70	0			
Limb discomfort								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscular weakness								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Trigger finger								
Europe	1	(0.1)	1	0.23	3	(0.3)	3	0.44
North America	5	(0.7)	5	1.04	1	(0.1)	1	0.15
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	3	(0.7)	3	1.27	1	(0.2)	3	0.68
Joint effusion								
Europe	1	(0.1)	2	0.37	0			
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal stenosis								
Europe	1	(0.1)	2	0.36	1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	3	1.16	0			
Acquired claw toe								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bursitis								
Europe	1	(0.1)	1	0.10	3	(0.3)	3	0.45
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.15
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Diastasis recti abdominis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Foot deformity								
Europe	1	(0.1)	2	0.20	2	(0.2)	2	0.36
North America	2	(0.3)	3	0.53	1	(0.1)	1	0.14
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Meniscopathy								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Psoriatic arthropathy								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tendon disorder								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.18
North America	0				0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Arthritis								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.49
North America	4	(0.6)	4	0.67	2	(0.3)	2	0.58
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.96	1	(0.2)	1	0.23
Costochondritis								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Exostosis								
Europe	1	(0.1)	1	0.11	0			
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Groin pain								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.34
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Musculoskeletal stiffness								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.1)	1	0.27	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	2	(0.5)	2	0.70	2	(0.4)	2	0.61
Myositis								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteopenia								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Plantar fasciitis								
Europe	1	(0.1)	2	0.21	1	(0.1)	1	0.11
North America	3	(0.4)	3	0.52	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Polyarthritis								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal pain								
Europe	1	(0.1)	1	0.11	4	(0.5)	4	0.53
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthropathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Axillary mass								
Europe	0				0			
North America	1	(0.1)	1	0.22	1	(0.1)	1	0.15

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone cyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Bone pain								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical spinal stenosis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chondromalacia								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Coccydynia								
Europe	0				0			
North America	2	(0.3)	2	0.38	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Dupuytren's contracture								
Europe	0				1	(0.1)	1	0.12
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Facet joint syndrome								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Fistula								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Flank pain								
Europe	0				0			
North America	1	(0.1)	1	0.22	4	(0.6)	5	1.01
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.63
Haemarthrosis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc degeneration								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Intervertebral disc space narrowing								
Europe	0				0			
North America	0				1	(0.1)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Jaw disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Joint swelling								
Europe	0				1	(0.1)	1	0.12
North America	0				2	(0.3)	2	0.52
South America	0				0			
Africa	0				0			
Asia	0				0			
Limb deformity								
Europe	0				1	(0.1)	1	0.12

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Limb mass								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lumbar spinal stenosis								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Mastication disorder								
Europe	0				0			
North America	0				1	(0.1)	2	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscle contracture								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Muscle twitching								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Neuropathic arthropathy								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nodal osteoarthritis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.2)	1	0.39
Osteochondritis								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Osteoporosis								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Pain in jaw								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Periostitis								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Polymyalgia rheumatica								
Europe	0				1	(0.1)	3	0.59
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Rheumatoid arthritis								
Europe	0				2	(0.2)	2	0.33
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				1	(0.2)	1	0.39
Sacroiliitis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Scoliosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Soft tissue swelling								
Europe	0				0			
North America	1	(0.1)	3	0.65	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal retrolisthesis								
Europe	0				0			
North America	0				1	(0.1)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Synovial cyst								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.80	0			
Tenosynovitis								
Europe	0				3	(0.3)	3	0.33
North America	1	(0.1)	1	0.27	0			
South America	1	(0.8)	1	0.83	0			
Africa	0				1	(4.0)	1	6.75
Asia	0				5	(1.1)	6	1.54
Tenosynovitis stenosans								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Torticollis								
Europe	0				1	(0.1)	1	0.18
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vertebral osteophyte								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Nervous system disorders								
All								
Europe	86	(9.3)	124	18.64	73	(8.2)	95	14.64
North America	68	(9.9)	91	17.14	75	(11.3)	100	20.33
South America	13	(10.0)	18	24.11	10	(7.6)	13	16.37
Africa	5	(20.0)	9	59.88	3	(12.0)	4	26.99
Asia	35	(8.7)	56	22.23	46	(10.0)	114	39.95
Headache								
Europe	32	(3.5)	43	7.59	15	(1.7)	17	2.72
North America	17	(2.4)	22	4.36	24	(3.6)	26	5.60
South America	5	(3.9)	6	7.96	4	(3.1)	6	8.31
Africa	3	(12.0)	5	33.27	3	(12.0)	4	26.99
Asia	13	(3.2)	16	5.30	18	(3.9)	27	8.00
Dizziness								
Europe	14	(1.5)	19	2.56	15	(1.7)	20	3.07
North America	15	(2.2)	15	2.52	10	(1.5)	12	2.55
South America	3	(2.3)	6	8.14	1	(0.8)	1	1.30
Africa	1	(4.0)	2	13.31	0			
Asia	7	(1.7)	9	3.64	13	(2.8)	14	4.57
Sciatica								
Europe	5	(0.5)	5	0.78	8	(0.9)	8	1.14
North America	4	(0.6)	4	0.71	4	(0.6)	5	0.85
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	1.48	0			
Carpal tunnel syndrome								
Europe	5	(0.5)	5	0.63	2	(0.2)	2	0.35
North America	4	(0.6)	4	0.67	5	(0.8)	5	1.07
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Syncope								
Europe	5	(0.5)	5	0.61	1	(0.1)	1	0.12
North America	2	(0.3)	2	0.43	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tremor								
Europe	4	(0.4)	4	0.42	2	(0.2)	2	0.30
North America	4	(0.6)	5	0.86	2	(0.3)	2	0.40
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	4	(1.0)	4	1.45	6	(1.3)	57	22.06
Diabetic neuropathy								
Europe	3	(0.3)	3	0.41	3	(0.3)	3	0.46
North America	0				5	(0.7)	5	0.85
South America	2	(1.5)	2	2.68	2	(1.5)	2	2.02
Africa	0				0			
Asia	1	(0.3)	1	0.55	2	(0.4)	2	0.76
Paraesthesia								
Europe	3	(0.3)	3	0.40	3	(0.3)	3	0.48
North America	5	(0.8)	6	0.91	5	(0.7)	5	0.85
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
Cerebrovascular disorder								
Europe	2	(0.2)	2	0.31	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysgeusia								
Europe	2	(0.2)	2	0.31	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Memory impairment								
Europe	2	(0.2)	2	0.31	0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Autonomic nervous system imbalance								
Europe	2	(0.2)	2	0.41	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervicobrachial syndrome								
Europe	2	(0.2)	2	0.41	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypoaesthesia								
Europe	2	(0.2)	2	0.29	3	(0.3)	3	0.56
North America	4	(0.6)	6	1.02	3	(0.4)	4	0.58
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	4	1.49	4	(0.9)	4	1.24
Carotid artery stenosis								
Europe	2	(0.2)	2	0.20	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Migraine								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.22
North America	4	(0.5)	5	1.19	4	(0.6)	4	1.04
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Cerebral arteriosclerosis								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vascular encephalopathy								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus headache								
Europe	1	(0.1)	1	0.23	0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Speech disorder								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Neuralgia								
Europe	1	(0.1)	1	0.18	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Somnolence								
Europe	1	(0.1)	1	0.18	0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Amnesia								
Europe	1	(0.1)	1	0.10	0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebral atrophy								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cognitive disorder								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Disturbance in attention								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	9	4.92	0			
Intracranial pressure increased								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Balance disorder								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Burning sensation								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.20
North America	1	(0.1)	1	0.27	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.23
Cerebral haemorrhage								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical radiculopathy								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dizziness postural								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Neuropathy peripheral								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.38
North America	5	(0.7)	6	1.29	8	(1.2)	8	1.46
South America	0				0			
Africa	0				0			
Asia	0				0			
Post herpetic neuralgia								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.1)	1	0.22	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Presyncope								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.34
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Transient ischaemic attack								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Trigeminal neuralgia								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ageusia								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Anosmia								
Europe	0				1	(0.1)	1	0.18
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Basilar migraine								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Brain injury								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Carotid arteriosclerosis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Carotid artery aneurysm								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Cerebral artery embolism								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebral infarction								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebrovascular accident								
Europe	0				1	(0.1)	1	0.11
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Cluster headache								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dementia Alzheimer's type								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Encephalopathy								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Essential tremor								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial nerve disorder								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial paralysis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Haemorrhage intracranial								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hemiparesis								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoglycaemic coma								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoglycaemic seizure								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Hypoglycaemic unconsciousness								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyporeflexia								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Hypotonia								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ischaemic stroke								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lethargy								
Europe	0				0			
North America	0				2	(0.3)	2	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Loss of consciousness								
Europe	0				1	(0.1)	1	0.11
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Lumbar radiculopathy								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	2	(0.3)	3	0.43
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Mental impairment								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Meralgia paraesthetica								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Morton's neuralgia								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Myelopathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Neuroglycopenia								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	3	0.45
South America	0				0			
Africa	0				0			
Asia	0				0			
Ophthalmic migraine								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Orthostatic tremor								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Parkinsonian gait								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Peripheral paralysis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Piriformis syndrome								
Europe	0				0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Radiculopathy								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Restless legs syndrome								
Europe	0				0			
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Sleep deficit								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Tension headache								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	3	0.74	0			
Thalamic infarction								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombotic stroke								
Europe	0				2	(0.2)	2	0.31
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vascular headache								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vertebral artery occlusion								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
White matter lesion								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injury, poisoning and procedural complications								
All								
Europe	82	(8.9)	92	13.92	63	(7.0)	71	11.20
North America	63	(9.0)	87	17.32	61	(9.4)	74	17.14
South America	10	(7.9)	13	15.73	11	(8.5)	14	18.72
Africa	5	(20.0)	9	59.88	2	(8.0)	2	13.49
Asia	34	(8.5)	40	13.46	43	(9.4)	56	18.02
Vaccination complication								
Europe	12	(1.3)	12	2.03	13	(1.4)	16	2.53
North America	1	(0.1)	1	0.22	2	(0.3)	3	0.82
South America	0				0			
Africa	1	(4.0)	4	26.61	0			
Asia	6	(1.5)	7	2.15	14	(3.0)	19	5.66
Accidental overdose								
Europe	8	(0.9)	9	1.76	1	(0.1)	1	0.19
North America	5	(0.7)	5	1.20	2	(0.3)	2	0.63
South America	0				1	(0.8)	2	2.85
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Prescribed overdose								
Europe	5	(0.6)	5	1.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Contusion								
Europe	5	(0.5)	6	0.63	1	(0.1)	1	0.12
North America	3	(0.4)	3	0.52	2	(0.3)	2	0.48
South America	1	(0.8)	1	1.32	0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	6	(1.5)	6	2.31	6	(1.3)	6	1.70
Incorrect dose administered								
Europe	4	(0.5)	4	0.88	1	(0.1)	1	0.11
North America	2	(0.3)	2	0.46	2	(0.3)	3	0.84
South America	0				2	(1.5)	3	3.91
Africa	0				0			
Asia	0				0			
Fall								
Europe	4	(0.4)	4	0.61	3	(0.3)	4	0.62
North America	14	(2.0)	14	2.41	7	(1.1)	7	1.28
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.70	1	(0.2)	1	0.40
Hand fracture								
Europe	4	(0.4)	4	0.58	0			
North America	2	(0.3)	2	0.53	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Skin laceration								
Europe	3	(0.3)	3	0.32	1	(0.1)	1	0.22
North America	3	(0.4)	3	0.60	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Road traffic accident								
Europe	2	(0.2)	2	0.29	0			
North America	3	(0.4)	4	0.92	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Ligament sprain								
Europe	2	(0.2)	2	0.33	4	(0.4)	4	0.66
North America	6	(0.8)	6	1.32	1	(0.1)	1	0.14
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	3	(0.7)	3	1.11	3	(0.7)	3	1.04
Rib fracture								
Europe	2	(0.2)	2	0.29	1	(0.1)	1	0.11
North America	2	(0.3)	2	0.37	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	2	(0.2)	2	0.21	2	(0.2)	2	0.30
North America	0				2	(0.3)	2	0.60
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	2	(0.4)	2	0.76
Accidental underdose								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthropod bite								
Europe	1	(0.1)	1	0.20	2	(0.2)	2	0.33
North America	2	(0.3)	2	0.45	2	(0.3)	2	0.58
South America	0				0			
Africa	0				0			
Asia	0				0			
Extra dose administered								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Epicondylitis								
Europe	1	(0.1)	1	0.23	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Product administration error								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.11
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Product dispensing error								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Procedural complication								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Thermal burn								
Europe	1	(0.1)	1	0.19	0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	1	(0.2)	1	0.23
Craniocerebral injury								
Europe	1	(0.1)	1	0.18	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Subcutaneous haematoma								
Europe	1	(0.1)	1	0.18	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Femoral neck fracture								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Foot fracture								
Europe	1	(0.1)	1	0.10	0			
North America	2	(0.3)	2	0.46	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.58
Hip fracture								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Inflammation of wound								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury of conjunctiva								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Multiple injuries								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Penile contusion								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural complication								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural inflammation								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Procedural pain								
Europe	1	(0.1)	1	0.10	0			
North America	3	(0.4)	3	0.78	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Tendon rupture								
Europe	1	(0.1)	1	0.10	0			
North America	1	(0.1)	1	0.25	1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper limb fracture								
Europe	1	(0.1)	1	0.10	0			
North America	2	(0.3)	2	0.30	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Ankle fracture								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	3	(0.5)	3	0.46	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical vertebral fracture								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye injury								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fibula fracture								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				1	(0.2)	1	0.34
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Injury								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Joint injury								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	1	(0.1)	1	0.23	3	(0.5)	3	0.63
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.2)	1	0.25	0			
Limb injury								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.46
North America	2	(0.3)	2	0.43	2	(0.3)	3	0.71
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.5)	2	0.66	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Meniscus injury								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.21
North America	0				2	(0.3)	2	0.28
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Post procedural fistula								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural haemorrhage								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural hypothyroidism								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Radius fracture								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.22
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Skin abrasion								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.22
North America	4	(0.6)	7	1.48	2	(0.3)	2	0.42
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	1.36	2	(0.5)	2	0.81
Tooth fracture								
Europe	1	(0.1)	1	0.11	0			
North America	2	(0.3)	2	0.38	2	(0.3)	2	0.49
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Traumatic haematoma								
Europe	1	(0.1)	1	0.11	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Anaemia postoperative								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Animal bite								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.63
Animal scratch								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthropod sting								
Europe	0				0			
North America	2	(0.3)	2	0.38	1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Back injury								
Europe	0				1	(0.1)	1	0.22
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone contusion								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Burn oral cavity								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.2)	1	0.25	0			
Burns first degree								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Chillblains								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.23
Clavicle fracture								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Concussion								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Corneal abrasion								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Crush injury								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Deafness traumatic								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Exposure to SARS-CoV-2								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Face injury								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	1	(0.2)	1	0.39
Facial bones fracture								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gun shot wound								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Head injury								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Heat illness								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	3	(0.6)	4	1.03
Heat stroke								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Humerus fracture								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Intentional overdose								
Europe	0				0			
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Intentional product use issue								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Ligament rupture								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Lower limb fracture								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medication error								
Europe	0				1	(0.1)	1	0.18
North America	0				1	(0.2)	1	0.34
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Muscle contusion								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Muscle injury								
Europe	0				2	(0.2)	2	0.37
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscle strain								
Europe	0				4	(0.4)	4	0.70
North America	0				1	(0.1)	1	0.14
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Neck injury								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nerve injury								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Overdose								
Europe	0				1	(0.1)	1	0.18
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				1	(0.8)	1	1.30
Africa	2	(8.0)	2	13.31	0			
Asia	1	(0.2)	1	0.41	0			
Periprocedural myocardial infarction								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural haematuria								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural stroke								
Europe	0				0			
North America	0				1	(0.1)	1	0.15

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural swelling								
Europe	0				1	(0.1)	2	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post-traumatic neck syndrome								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Radiation skin injury								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Scar								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Scratch								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Seroma								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Soft tissue injury								
Europe	0				2	(0.2)	2	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Spinal column injury								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal compression fracture								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Stab wound								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Subdural haematoma								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sunburn								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tendon injury								
Europe	0				0			
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Tibia fracture								
Europe	0				0			
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Underdose								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				4	(0.6)	4	1.00
South America	0				1	(0.8)	1	1.30
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Wound dehiscence								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Wrist fracture								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Wrong dose								
Europe	0				0			
North America	0				0			
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				0			
Wrong product administered								
Europe	0				2	(0.2)	2	0.44
North America	1	(0.1)	2	0.46	3	(0.5)	3	0.96
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
General disorders and administration site conditions								
All								
Europe	79	(8.6)	109	17.41	69	(7.7)	92	14.44
North America	90	(13.0)	142	28.45	66	(9.9)	104	19.35
South America	7	(5.5)	8	10.11	4	(3.0)	5	5.46
Africa	4	(16.0)	6	39.92	1	(4.0)	1	6.75
Asia	60	(15.0)	98	36.54	68	(14.8)	142	46.83
Pyrexia								
Europe	13	(1.4)	14	2.28	10	(1.1)	10	1.81
North America	8	(1.2)	8	1.62	6	(0.9)	6	1.15
South America	0				1	(0.8)	1	1.43
Africa	1	(4.0)	1	6.65	0			
Asia	19	(4.8)	20	7.21	26	(5.7)	28	7.94
Fatigue								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	11	(1.2)	13	2.29	3	(0.3)	3	0.42
North America	19	(2.8)	21	3.81	12	(1.8)	12	2.22
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.35
Asthenia								
Europe	6	(0.6)	6	0.87	6	(0.7)	6	0.99
North America	0				1	(0.2)	1	0.29
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	3	(0.7)	3	0.90	3	(0.7)	3	0.86
Influenza like illness								
Europe	5	(0.6)	6	1.06	4	(0.5)	4	0.55
North America	1	(0.1)	1	0.22	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Medical device site reaction								
Europe	5	(0.5)	7	1.18	1	(0.1)	1	0.12
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Chest pain								
Europe	4	(0.4)	4	0.42	4	(0.4)	4	0.67
North America	7	(1.0)	7	1.22	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	3	1.27	1	(0.2)	1	0.23
Pain								
Europe	3	(0.3)	3	0.65	3	(0.3)	3	0.41
North America	8	(1.1)	9	1.83	8	(1.2)	8	1.40
South America	0				1	(0.8)	2	2.60
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.45	1	(0.2)	1	0.23
Oedema peripheral								
Europe	3	(0.3)	3	0.52	4	(0.4)	4	0.63
North America	11	(1.6)	11	1.92	5	(0.7)	6	1.03
South America	1	(0.8)	1	1.32	1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	3	(0.7)	3	1.37	0			
Injection site reaction								
Europe	3	(0.3)	4	0.66	0			
North America	6	(0.9)	19	4.65	5	(0.8)	7	1.37
South America	2	(1.5)	2	2.64	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	4	(0.9)	4	1.64	1	(0.2)	1	0.23
Medical device site bruise								
Europe	3	(0.3)	3	0.44	1	(0.1)	1	0.12
North America	4	(0.6)	6	1.17	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug intolerance								
Europe	3	(0.3)	3	0.32	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Inflammation								
Europe	2	(0.2)	2	0.41	2	(0.2)	2	0.22
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site haematoma								
Europe	2	(0.2)	6	1.12	3	(0.3)	8	1.49
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Swelling face								
Europe	2	(0.2)	2	0.33	0			
North America	0				2	(0.3)	2	0.40
South America	0				0			
Africa	0				0			
Asia	0				0			
Malaise								
Europe	2	(0.2)	2	0.33	4	(0.5)	6	0.85
North America	5	(0.7)	6	1.04	1	(0.1)	1	0.14
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	8	(2.0)	9	3.06	10	(2.1)	53	19.52
Medical device site pruritus								
Europe	2	(0.2)	2	0.33	1	(0.1)	1	0.22
North America	3	(0.4)	3	0.52	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.61

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Discomfort								
Europe	2	(0.2)	2	0.29	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	8	3.24
Hunger								
Europe	2	(0.2)	3	0.40	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	5	(1.3)	5	1.54	3	(0.6)	4	1.35
Medical device site dermatitis								
Europe	2	(0.2)	2	0.29	0			
North America	2	(0.3)	5	0.89	2	(0.3)	2	0.49
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	3	(0.8)	3	1.50	8	(1.7)	15	3.87
Vaccination site pain								
Europe	2	(0.2)	3	0.40	3	(0.3)	3	0.45
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	8	(2.0)	9	3.33	5	(1.1)	5	1.87
Gait disturbance								
Europe	2	(0.2)	2	0.21	0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Feeling abnormal								
Europe	1	(0.1)	1	0.20	0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	3	0.74	1	(0.2)	1	0.23
Multiple organ dysfunction syndrome								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site haematoma								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.12
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site pain								
Europe	1	(0.1)	1	0.23	3	(0.3)	3	0.51
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site rash								
Europe	1	(0.1)	1	0.23	0			
North America	2	(0.3)	2	0.55	4	(0.7)	4	1.29
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.64	4	(0.8)	4	1.55
Injection site pain								
Europe	1	(0.1)	1	0.19	6	(0.7)	6	1.07
North America	1	(0.1)	1	0.25	6	(0.9)	24	3.65
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.41
Chills								
Europe	1	(0.1)	1	0.18	0			
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Medical device site erythema								
Europe	1	(0.1)	1	0.18	5	(0.5)	6	1.18
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Localised oedema								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chest discomfort								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.30
North America	4	(0.6)	4	0.78	0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.5)	2	0.66	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Feeling hot								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site hypersensitivity								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site eczema								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Medical device site haemorrhage								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.50	2	(0.4)	2	0.45
Peripheral swelling								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.22
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	3	1.07	2	(0.5)	2	0.81
Swelling								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Thirst								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.19
North America	2	(0.3)	2	0.48	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Application site bruise								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Application site pruritus								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Axillary pain								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Condition aggravated								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Cyst								
Europe	0				0			
North America	0				2	(0.3)	2	0.43
South America	0				0			
Africa	0				0			
Asia	0				0			
Death								
Europe	0				2	(0.2)	2	0.22
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Early satiety								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial pain								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Hernia								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperthermia								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Implant site pruritus								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site bruising								
Europe	0				1	(0.1)	1	0.12
North America	3	(0.4)	3	0.66	4	(0.6)	4	0.69
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site dermatitis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site erythema								
Europe	0				2	(0.2)	2	0.23
North America	2	(0.3)	4	1.01	1	(0.1)	1	0.15
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Injection site haemorrhage								
Europe	0				0			
North America	1	(0.1)	1	0.25	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.23
Injection site hypertrophy								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Injection site induration								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Injection site mass								
Europe	0				1	(0.1)	1	0.22
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site oedema								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site pruritus								
Europe	0				0			
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	17	7.01	1	(0.2)	1	0.41
Injection site rash								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Injection site swelling								
Europe	0				0			
North America	2	(0.3)	2	0.47	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site urticaria								
Europe	0				0			
North America	1	(0.1)	2	0.55	1	(0.1)	1	0.15
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Medical device site hypersensitivity								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Medical device site inflammation								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site irritation								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Non-cardiac chest pain								
Europe	0				2	(0.2)	4	0.44
North America	0				2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Oedema								
Europe	0				0			
North America	1	(0.1)	1	0.23	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Oedema due to renal disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Procedural failure								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Systemic inflammatory response syndrome								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site erythema								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site inflammation								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site pruritus								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site reaction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Vessel puncture site bruise								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Xerosis								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
All								
Europe	65	(7.1)	97	15.60	56	(6.2)	68	10.74
North America	47	(6.8)	58	10.91	40	(6.1)	49	10.85
South America	4	(3.1)	4	4.83	5	(3.8)	10	9.50
Africa	2	(8.0)	2	13.31	1	(4.0)	1	6.75
Asia	14	(3.4)	16	5.12	20	(4.4)	25	8.06
Oropharyngeal pain								
Europe	13	(1.4)	14	2.19	8	(0.9)	8	1.27
North America	6	(0.9)	6	0.98	7	(1.1)	8	2.01
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	5	(1.2)	6	1.98	3	(0.7)	4	1.08
Cough								
Europe	10	(1.1)	12	1.75	14	(1.5)	15	2.66
North America	10	(1.4)	11	2.18	9	(1.3)	9	1.72
South America	1	(0.8)	1	1.36	0			
Africa	1	(4.0)	1	6.65	0			
Asia	4	(1.0)	4	1.32	5	(1.1)	6	1.87
Respiratory disorder								
Europe	8	(0.9)	8	1.62	6	(0.7)	6	1.03
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Rhinorrhoea								
Europe	8	(0.9)	11	1.66	7	(0.8)	7	1.23
North America	4	(0.5)	4	0.86	5	(0.8)	5	1.24
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Epistaxis								
Europe	4	(0.4)	8	1.52	1	(0.1)	2	0.35
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.41	1	(0.2)	2	0.45
Dyspnoea								
Europe	3	(0.3)	3	0.58	6	(0.7)	6	0.87
North America	5	(0.8)	5	0.86	6	(0.9)	7	1.46
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.23
Sleep apnoea syndrome								
Europe	3	(0.3)	3	0.40	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	4	(0.6)	4	0.68	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Productive cough								
Europe	3	(0.3)	3	0.47	0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				3	(0.6)	3	1.00
Emphysema								
Europe	2	(0.2)	2	0.31	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Pulmonary fibrosis								
Europe	2	(0.2)	3	0.42	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus pain								
Europe	2	(0.2)	3	0.42	0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Sneezing								
Europe	2	(0.2)	2	0.41	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic obstructive pulmonary disease								
Europe	2	(0.2)	2	0.37	1	(0.1)	1	0.12
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Rhinitis allergic								
Europe	2	(0.2)	2	0.33	1	(0.1)	1	0.19
North America	0				2	(0.3)	2	0.55
South America	0				1	(0.7)	5	3.58
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				2	(0.4)	2	0.79
Nasal congestion								
Europe	2	(0.2)	2	0.29	2	(0.2)	2	0.34
North America	6	(0.9)	6	0.99	3	(0.4)	3	0.43
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.50	0			
Asthma								
Europe	1	(0.1)	1	0.20	0			
North America	3	(0.4)	4	0.69	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Nasal septum deviation								
Europe	1	(0.1)	1	0.20	0			
North America	1	(0.1)	1	0.22	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleurisy								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary hypertension								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchial hyperreactivity								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper-airway cough syndrome								
Europe	1	(0.1)	1	0.23	0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Acute respiratory failure								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.18	0			
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Nasal obstruction								
Europe	1	(0.1)	1	0.18	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Respiratory failure								
Europe	1	(0.1)	1	0.18	2	(0.2)	2	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper respiratory tract inflammation								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acquired diaphragmatic eventration								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchiectasis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Laryngeal cyst								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nasal dryness								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Nasal turbinate hypertrophy								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary embolism								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus congestion								
Europe	1	(0.1)	2	0.21	0			
North America	5	(0.7)	5	1.18	2	(0.3)	2	0.49
South America	0				0			
Africa	0				0			
Asia	0				0			
Throat irritation								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Acute pulmonary oedema								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Allergic bronchitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Allergic cough								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				1	(0.2)	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Aphonia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchitis chronic								
Europe	0				2	(0.2)	2	0.29
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchospasm								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Dry throat								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysphonia								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	2	2.60
Africa	0				0			
Asia	0				0			
Dyspnoea exertional								
Europe	0				2	(0.2)	2	0.22
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Haemoptysis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hiccups								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Increased viscosity of upper respiratory secretion								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Interstitial lung disease								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Lung disorder								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Paranasal cyst								
Europe	0				1	(0.1)	1	0.18
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Paranasal sinus discomfort								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleural disorder								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleural effusion								
Europe	0				2	(0.2)	2	0.21
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Pleuritic pain								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary congestion								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary mass								
Europe	0				2	(0.2)	2	0.22
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Respiratory tract inflammation								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye disorders								
All								
Europe	59	(6.5)	84	12.68	65	(7.2)	80	12.69
North America	62	(8.8)	73	15.01	54	(8.2)	76	16.94
South America	10	(7.8)	10	12.75	7	(5.4)	8	10.08
Africa	5	(20.0)	8	53.22	8	(32.0)	12	80.96
Asia	40	(10.1)	50	19.98	46	(10.1)	60	20.96
Diabetic retinopathy								
Europe	15	(1.7)	17	2.69	23	(2.5)	25	4.29
North America	20	(2.9)	20	4.22	21	(3.2)	22	4.71
South America	4	(3.1)	4	5.32	4	(3.1)	4	5.45
Africa	4	(16.0)	5	33.27	5	(20.0)	6	40.48
Asia	21	(5.3)	24	10.56	19	(4.1)	19	6.70
Cataract								
Europe	14	(1.5)	18	2.50	8	(0.9)	9	1.22
North America	6	(0.9)	6	1.04	10	(1.5)	11	1.87
South America	2	(1.5)	2	2.64	0			
Africa	0				2	(8.0)	2	13.49

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	6	(1.5)	7	2.34	7	(1.5)	8	2.81
Retinopathy hypertensive								
Europe	5	(0.6)	6	1.06	5	(0.5)	5	0.81
North America	1	(0.2)	1	0.15	0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Macular oedema								
Europe	4	(0.4)	5	0.95	3	(0.3)	3	0.39
North America	7	(1.0)	7	1.53	2	(0.3)	2	0.48
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Eye pain								
Europe	3	(0.3)	3	0.39	2	(0.2)	2	0.29
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Age-related macular degeneration								
Europe	2	(0.2)	2	0.30	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic retinal oedema								
Europe	2	(0.2)	2	0.41	5	(0.5)	6	0.97
North America	2	(0.3)	2	0.50	2	(0.3)	2	0.28
South America	0				0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.2)	1	0.41	2	(0.4)	2	0.76
Arteriosclerotic retinopathy								
Europe	2	(0.2)	2	0.33	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dry eye								
Europe	2	(0.2)	2	0.33	0			
North America	3	(0.5)	3	0.46	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.70	6	(1.3)	6	1.54
Blepharitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	2	(0.2)	2	0.29	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.50	0			
Eye inflammation								
Europe	2	(0.2)	2	0.29	2	(0.2)	2	0.35
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Astigmatism								
Europe	2	(0.2)	3	0.31	1	(0.1)	1	0.18
North America	0				4	(0.6)	4	0.90
South America	0				0			
Africa	0				0			
Asia	0				0			
Presbyopia								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.20
North America	0				2	(0.3)	2	0.62
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal deposits								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal haemorrhage								
Europe	1	(0.1)	1	0.20	0			
North America	2	(0.3)	2	0.38	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Retinal vascular disorder								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Non-proliferative retinopathy								
Europe	1	(0.1)	2	0.37	2	(0.2)	2	0.42
North America	2	(0.3)	2	0.55	1	(0.2)	1	0.34
South America	0				1	(0.8)	1	1.30

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Lacrimation increased								
Europe	1	(0.1)	1	0.18	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Myopia								
Europe	1	(0.1)	1	0.18	1	(0.1)	1	0.11
North America	0				2	(0.3)	2	0.48
South America	0				0			
Africa	0				0			
Asia	0				0			
Amaurosis fugax								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Conjunctival suffusion								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Glaucoma								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.12
North America	3	(0.4)	3	0.58	2	(0.3)	2	0.48
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				2	(0.4)	2	0.77
Maculopathy								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitreous opacities								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Conjunctival erosion								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diplopia								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Optic disc vascular disorder								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post thrombotic retinopathy								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal aneurysm								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal tear								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitreous detachment								
Europe	1	(0.1)	1	0.11	0			
North America	2	(0.3)	2	0.38	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.77
Acquired epiblepharon								
Europe	0				0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Angle closure glaucoma								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Asthenopia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Cataract nuclear								
Europe	0				0			
North America	2	(0.3)	2	0.49	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chorioretinal atrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Conjunctival haemorrhage								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	2	(0.5)	2	1.00	0			
Conjunctival hyperaemia								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Conjunctivitis allergic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	3	0.91	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Corneal bleeding								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Corneal erosion								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Cystoid macular oedema								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Dacryoadenitis acquired								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dry age-related macular degeneration								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Epiretinal membrane								
Europe	0				0			
North America	2	(0.3)	2	0.49	3	(0.5)	3	0.74
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye discharge								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Eye irritation								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Eye pruritus								
Europe	0				0			
North America	0				1	(0.1)	2	0.52
South America	0				0			
Africa	0				0			
Asia	0				0			
Eyelid oedema								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypermetropia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Macular degeneration								
Europe	0				1	(0.1)	1	0.11
North America	0				2	(0.3)	2	0.43
South America	0				0			
Africa	0				0			
Asia	0				0			
Macular hole								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Meibomianitis								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Normal tension glaucoma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.2)	1	0.23
Ocular hyperaemia								
Europe	0				0			
North America	2	(0.3)	3	0.72	1	(0.1)	2	0.52
South America	0				0			
Africa	0				0			
Asia	0				0			
Ocular hypertension								
Europe	0				2	(0.2)	3	0.56
North America	2	(0.3)	2	0.37	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ocular ischaemic syndrome								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Open angle glaucoma								
Europe	0				0			
North America	0				1	(0.2)	2	0.58
South America	0				0			
Africa	0				0			
Asia	0				0			
Ophthalmic vein thrombosis								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Optic disc haemorrhage								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Photophobia								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Photopsia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Posterior capsule opacification								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Pterygium								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal artery occlusion								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Retinal degeneration								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Retinal detachment								
Europe	0				1	(0.1)	1	0.12
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal drusen								
Europe	0				0			
North America	1	(0.1)	1	0.23	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal exudates								
Europe	0				0			
North America	1	(0.1)	1	0.22	1	(0.2)	1	0.29
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Retinal scar								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal vein occlusion								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinopathy								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Scintillating scotoma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Uveitis								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Vision blurred								
Europe	0				1	(0.1)	1	0.12
North America	4	(0.6)	4	0.83	2	(0.3)	2	0.43
South America	1	(0.8)	1	1.32	0			
Africa	0				1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.55	1	(0.2)	1	0.23
Visual acuity reduced								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Visual impairment								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	9	3.64
Vitreous degeneration								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitreous floaters								
Europe	0				1	(0.1)	1	0.22
North America	0				1	(0.2)	1	0.34
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Vitreous haemorrhage								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	2	(0.5)	2	0.86	0			
Metabolism and nutrition disorders								
All								
Europe	53	(5.8)	73	9.59	47	(5.2)	59	8.29
North America	37	(5.5)	46	8.40	35	(5.3)	40	7.61
South America	14	(11.2)	15	16.90	15	(11.4)	16	18.73
Africa	2	(8.0)	2	13.31	2	(8.0)	2	13.49
Asia	26	(6.3)	27	9.40	35	(7.7)	52	15.48
Vitamin D deficiency								
Europe	14	(1.5)	14	1.53	11	(1.2)	11	1.49
North America	3	(0.4)	3	0.58	2	(0.3)	2	0.29
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Hypoglycaemia								
Europe	8	(0.9)	11	2.02	6	(0.7)	9	1.24
North America	3	(0.4)	7	1.79	4	(0.6)	4	1.03
South America	2	(1.5)	3	4.00	0			
Africa	0				0			
Asia	5	(1.2)	5	1.70	13	(2.8)	27	7.79

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperlipidaemia								
Europe	7	(0.8)	7	0.80	4	(0.5)	4	0.53
North America	3	(0.5)	3	0.46	7	(1.0)	7	1.14
South America	0				0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	3	(0.7)	3	1.24	1	(0.2)	1	0.41
Vitamin B12 deficiency								
Europe	6	(0.6)	6	0.60	1	(0.1)	1	0.11
North America	5	(0.8)	5	0.76	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gout								
Europe	4	(0.4)	5	0.52	1	(0.1)	1	0.12
North America	0				5	(0.7)	6	0.87
South America	0				0			
Africa	0				0			
Asia	0				0			
Iron deficiency								
Europe	4	(0.4)	4	0.41	3	(0.3)	3	0.32
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertriglyceridaemia								
Europe	3	(0.3)	3	0.41	2	(0.2)	2	0.29
North America	0				0			
South America	2	(1.6)	2	2.15	3	(2.3)	3	4.03
Africa	0				0			
Asia	5	(1.2)	5	1.40	3	(0.7)	3	0.68
Dyslipidaemia								
Europe	3	(0.3)	3	0.42	6	(0.7)	6	0.87
North America	3	(0.5)	3	0.46	0			
South America	7	(5.6)	7	7.28	8	(6.1)	8	9.24
Africa	0				0			
Asia	8	(1.9)	9	3.20	3	(0.7)	3	1.04
Decreased appetite								
Europe	3	(0.3)	3	0.40	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	4	(0.6)	4	0.72
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperglycaemia								
Europe	3	(0.3)	3	0.46	5	(0.5)	5	0.84
North America	2	(0.3)	3	0.66	3	(0.5)	3	0.73

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.02
Africa	0				0			
Asia	0				4	(0.9)	4	1.08
Hyperuricaemia								
Europe	3	(0.3)	3	0.38	2	(0.2)	2	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	1	(0.2)	1	0.23
Folate deficiency								
Europe	2	(0.2)	2	0.20	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Increased appetite								
Europe	2	(0.2)	2	0.21	2	(0.2)	3	0.49
North America	1	(0.2)	1	0.15	3	(0.4)	3	0.66
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Fluid retention								
Europe	1	(0.1)	1	0.20	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypercholesterolaemia								
Europe	1	(0.1)	1	0.20	2	(0.2)	2	0.34
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.28
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Hypoalbuminaemia								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypokalaemia								
Europe	1	(0.1)	1	0.20	0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyponatraemia								
Europe	1	(0.1)	1	0.20	0			
North America	2	(0.3)	2	0.50	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Zinc deficiency								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Hyperkalaemia								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.40
North America	3	(0.4)	4	0.69	4	(0.6)	4	0.88
South America	1	(0.8)	1	0.83	0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	2	(0.5)	2	0.66	2	(0.5)	2	0.63
Abnormal weight gain								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Appetite disorder								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	2	0.45
Dehydration								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	2	(0.4)	3	1.00
Diabetes mellitus								
Europe	0				0			
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetes mellitus inadequate control								
Europe	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrolyte imbalance								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Food craving								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperammonaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Hypercalcaemia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypernatraemia								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Insulin resistance								
Europe	0				1	(0.1)	1	0.22
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Lactic acidosis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Lipomatosis								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Magnesium deficiency								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malnutrition								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Metabolic acidosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Metabolic disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Obesity								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.79
Vitamin B complex deficiency								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Skin and subcutaneous tissue disorders								
All								
Europe	51	(5.5)	53	8.12	39	(4.4)	46	6.77
North America	34	(4.9)	38	7.20	43	(6.4)	51	9.88
South America	1	(0.8)	1	1.32	5	(3.9)	5	6.76
Africa	1	(4.0)	1	6.65	0			
Asia	36	(9.0)	38	13.98	41	(8.9)	53	17.40
Rash								
Europe	6	(0.7)	6	1.15	3	(0.3)	3	0.35
North America	5	(0.7)	5	0.84	6	(0.9)	7	1.16
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.16	2	(0.4)	2	0.58
Pruritus								
Europe	5	(0.5)	5	0.60	3	(0.3)	3	0.34
North America	2	(0.3)	2	0.38	5	(0.7)	5	0.99
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.2)	1	0.41	3	(0.7)	3	1.20
Urticaria								
Europe	4	(0.4)	4	0.48	5	(0.6)	5	0.67
North America	1	(0.1)	1	0.22	5	(0.8)	5	1.11
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.5)	2	0.86	1	(0.2)	1	0.23
Eczema								
Europe	4	(0.4)	4	0.42	3	(0.3)	3	0.50
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	5	(1.2)	5	1.77	4	(0.9)	4	1.39
Dermatitis contact								
Europe	3	(0.3)	3	0.44	3	(0.3)	3	0.45
North America	2	(0.3)	2	0.43	4	(0.6)	4	0.79
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.5)	3	0.74	6	(1.2)	6	2.18
Skin ulcer								
Europe	2	(0.2)	2	0.31	1	(0.1)	1	0.11
North America	2	(0.3)	2	0.38	2	(0.3)	2	0.55
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Alopecia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	2	(0.2)	2	0.45	1	(0.1)	1	0.19
North America	6	(0.8)	6	1.18	2	(0.3)	2	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Dermatitis								
Europe	2	(0.2)	2	0.33	4	(0.5)	4	0.53
North America	2	(0.3)	2	0.41	2	(0.3)	3	0.67
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.64	1	(0.2)	1	0.39
Hyperkeratosis								
Europe	2	(0.2)	2	0.29	1	(0.1)	1	0.22
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Ingrowing nail								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.45
Umbilical haematoma								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blister								
Europe	1	(0.1)	1	0.23	0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.2)	1	0.23
Dermal cyst								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.12
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.61
Hidradenitis								
Europe	1	(0.1)	1	0.23	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Ingrown hair								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lichen sclerosus								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rash erythematous								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Skin irritation								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.22
North America	3	(0.4)	4	0.73	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin lesion								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Decubitus ulcer								
Europe	1	(0.1)	1	0.19	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperhidrosis								
Europe	1	(0.1)	1	0.18	3	(0.3)	3	0.49
North America	2	(0.3)	2	0.30	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	5	(1.2)	5	1.72	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Erythema								
Europe	1	(0.1)	1	0.10	2	(0.2)	2	0.34
North America	0				2	(0.3)	2	0.40
South America	0				0			
Africa	0				0			
Asia	0				0			
Livedo reticularis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nail bed inflammation								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Night sweats								
Europe	1	(0.1)	1	0.10	0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Dermatitis allergic								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Dry skin								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	0				3	(0.4)	3	0.54
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.04	1	(0.2)	1	0.39
Granuloma annulare								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipodystrophy acquired								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Psoriasis								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Skin exfoliation								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Acne								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Actinic keratosis								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Alopecia areata								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Angioedema								
Europe	0				3	(0.3)	3	0.44
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Asteatosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chronic spontaneous urticaria								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cold sweat								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	4	(1.0)	4	1.31	8	(1.6)	12	4.33
Cold urticaria								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Dermatitis atopic								
Europe	0				2	(0.2)	2	0.44
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic foot								
Europe	0				2	(0.2)	2	0.22
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug eruption								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Ecchymosis								
Europe	0				0			
North America	1	(0.1)	1	0.25	2	(0.3)	2	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemorrhage subcutaneous								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Intertrigo								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lentigo								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Leukoplakia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Lipohypertrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.63
Macule								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Miliaria								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.91	3	(0.7)	3	0.68
Myxoid cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.2)	1	0.25	0			
Neurodermatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Pruritus allergic								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Purpura								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Rash maculo-papular								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Rash papular								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Seborrhoea								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin discolouration								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Skin fissures								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Skin odour abnormal								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin reaction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Telangiectasia								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Urticaria contact								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Urticaria thermal								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Xeroderma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Cardiac 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	49	(5.3)	76	9.10	47	(5.3)	65	8.51
North America	31	(4.6)	40	6.97	19	(2.8)	31	5.62
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.43
Africa	0				1	(4.0)	1	6.75
Asia	14	(3.5)	16	6.72	16	(3.5)	17	5.37
Atrial fibrillation								
Europe	11	(1.2)	12	1.27	4	(0.4)	4	0.51
North America	1	(0.1)	1	0.22	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	1	(0.2)	1	0.23
Cardiac failure								
Europe	8	(0.9)	8	0.92	2	(0.2)	3	0.57
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronary artery disease								
Europe	8	(0.9)	8	0.91	5	(0.5)	5	0.67
North America	4	(0.6)	4	0.69	5	(0.7)	5	0.73
South America	0				0			
Africa	0				0			
Asia	0				0			
Angina pectoris								
Europe	6	(0.6)	6	0.74	1	(0.1)	1	0.11
North America	1	(0.1)	1	0.23	2	(0.3)	2	0.43
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Ventricular extrasystoles								
Europe	4	(0.4)	4	0.55	1	(0.1)	2	0.21
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.34	1	(0.2)	1	0.23
Acute myocardial infarction								
Europe	4	(0.4)	4	0.42	4	(0.5)	4	0.45
North America	4	(0.6)	4	0.79	3	(0.5)	3	0.70
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	1	(0.2)	1	0.35
Acute coronary syndrome								
Europe	3	(0.3)	3	0.32	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Myocardial infarction								
Europe	3	(0.3)	3	0.32	1	(0.1)	1	0.12
North America	1	(0.1)	1	0.22	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.81	1	(0.2)	1	0.23
Palpitations								
Europe	2	(0.2)	2	0.33	3	(0.3)	3	0.45
North America	4	(0.6)	4	0.71	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	3	(0.6)	3	1.02
Tachycardia								
Europe	2	(0.2)	2	0.20	3	(0.3)	3	0.33
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
Cardiac failure chronic								
Europe	2	(0.2)	2	0.21	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic valve sclerosis								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bundle branch block right								
Europe	1	(0.1)	1	0.23	5	(0.6)	6	0.81
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Cardiovascular disorder								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Atrioventricular block first degree								
Europe	1	(0.1)	1	0.19	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mitral valve stenosis								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Supraventricular extrasystoles								
Europe	1	(0.1)	1	0.19	1	(0.1)	1	0.12
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.66	0			
Arrhythmia								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.63
Arteriosclerosis coronary artery								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left ventricular hypertrophy								
Europe	1	(0.1)	1	0.10	2	(0.2)	2	0.29
North America	2	(0.3)	2	0.31	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Angina unstable								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.22
North America	2	(0.3)	2	0.31	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Aortic valve incompetence								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial flutter								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial thrombosis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic coronary syndrome								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronary artery occlusion								
Europe	1	(0.1)	1	0.11	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left atrial dilatation								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mitral valve incompetence								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.21
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Myocardial ischaemia								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.44
North America	0				0			
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pericardial effusion								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pericarditis								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus tachycardia								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tricuspid valve incompetence								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic valve calcification								
Europe	0				2	(0.2)	2	0.29
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial enlargement								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrioventricular block complete								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Bradycardia								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Bundle branch block left								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Cardiac arrest								
Europe	0				0			
North America	0				2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac dysfunction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Cardiac failure acute								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac failure congestive								
Europe	0				1	(0.1)	2	0.35
North America	3	(0.5)	3	0.46	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Cardiac flutter								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac perfusion defect								
Europe	0				0			
North America	0				1	(0.2)	2	0.58
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Cardiac ventricular thrombosis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardio-respiratory arrest								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiomegaly								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Coronary artery stenosis								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diastolic dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left atrial enlargement								
Europe	0				0			
North America	1	(0.1)	1	0.23	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Left ventricular dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.41
Sinus arrhythmia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus bradycardia								
Europe	0				2	(0.2)	2	0.22
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Subendocardial ischaemia								
Europe	0				2	(0.2)	2	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Supraventricular tachycardia								
Europe	0				0			
North America	2	(0.3)	2	0.37	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ventricular arrhythmia								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ventricular tachycardia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Vascular disorders								
All								
Europe	37	(4.0)	43	6.19	46	(5.1)	57	8.06
North America	22	(3.3)	24	4.18	13	(1.9)	17	2.85
South America	5	(3.9)	5	6.11	4	(3.1)	4	5.33
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	14	(3.5)	15	5.13	16	(3.6)	20	6.78
Hypertension								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	14	(1.5)	14	1.98	14	(1.6)	16	2.27
North America	10	(1.5)	10	1.97	8	(1.2)	9	1.72
South America	3	(2.4)	3	3.47	3	(2.3)	3	3.91
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	9	(2.2)	9	3.31	12	(2.7)	14	4.53
Peripheral arterial occlusive disease								
Europe	3	(0.3)	3	0.49	2	(0.2)	2	0.23
North America	1	(0.2)	2	0.31	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arteriosclerosis								
Europe	3	(0.3)	3	0.43	5	(0.6)	5	0.62
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
Hypotension								
Europe	3	(0.3)	3	0.40	2	(0.2)	2	0.29
North America	2	(0.3)	2	0.30	1	(0.1)	1	0.14
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Peripheral artery stenosis								
Europe	2	(0.2)	5	0.83	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Superficial vein thrombosis								
Europe	2	(0.2)	2	0.21	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic arteriosclerosis								
Europe	2	(0.2)	2	0.21	4	(0.4)	4	0.65
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic vascular disorder								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Haematoma								
Europe	1	(0.1)	1	0.20	3	(0.3)	3	0.48
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertensive crisis								
Europe	1	(0.1)	1	0.20	2	(0.2)	4	0.64
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral venous disease								
Europe	1	(0.1)	1	0.20	2	(0.2)	2	0.22
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Orthostatic hypotension								
Europe	1	(0.1)	1	0.18	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Venous stenosis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Brachiocephalic arteriosclerosis								
Europe	1	(0.1)	1	0.11	3	(0.3)	3	0.35
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Flushing								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral artery occlusion								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral coldness								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.50	1	(0.2)	1	0.23
Peripheral vascular disorder								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aneurysm								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic aneurysm								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Aortic stenosis								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Arterial insufficiency								
Europe	0				0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Blood pressure fluctuation								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood pressure inadequately controlled								
Europe	0				2	(0.2)	2	0.22
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Deep vein thrombosis								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hot flush								
Europe	0				1	(0.1)	1	0.19
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertensive urgency								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	2	0.28
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Iliac artery stenosis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intermittent claudication								
Europe	0				2	(0.2)	2	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Macroangiopathy								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Neovascularisation								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral artery aneurysm								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral ischaemia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Phlebitis								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombophlebitis								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombosis								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Varicose ulceration								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Varicose vein								
Europe	0				2	(0.2)	2	0.34
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Investigations								
All								
Europe	35	(3.8)	42	6.34	32	(3.6)	35	5.59
North America	47	(6.7)	53	10.70	30	(4.5)	31	6.35
South America	1	(0.8)	1	1.32	3	(2.3)	3	3.57
Africa	0				0			
Asia	11	(2.7)	13	4.25	14	(3.1)	19	6.66
SARS-CoV-2 test positive								
Europe	5	(0.6)	5	0.79	4	(0.4)	4	0.89
North America	2	(0.3)	2	0.47	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood creatinine increased								
Europe	5	(0.6)	5	0.86	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.87	0			
Blood triglycerides increased								
Europe	3	(0.3)	3	0.53	0			
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Blood pressure increased								
Europe	3	(0.3)	3	0.40	2	(0.2)	2	0.29
North America	2	(0.3)	2	0.55	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood immunoglobulin E increased								
Europe	3	(0.3)	3	0.30	3	(0.3)	3	0.32

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Weight increased								
Europe	3	(0.3)	3	0.30	4	(0.5)	4	0.53
North America	15	(2.1)	15	3.08	9	(1.4)	9	1.85
South America	0				3	(2.3)	3	3.57
Africa	0				0			
Asia	2	(0.5)	2	0.50	2	(0.4)	2	0.45
Occult blood								
Europe	2	(0.2)	2	0.29	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophil count increased								
Europe	1	(0.1)	1	0.20	1	(0.1)	2	0.44
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Angiogram								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aspartate aminotransferase increased								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.23
Blood cholesterol increased								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.22
North America	2	(0.3)	2	0.31	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Heart rate increased								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Hepatitis B virus test positive								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Low density lipoprotein increased								
Europe	1	(0.1)	1	0.23	0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
Arthroscopy								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Alanine aminotransferase increased								
Europe	1	(0.1)	1	0.18	0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.66	0			
Electrocardiogram T wave inversion								
Europe	1	(0.1)	1	0.10	0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
QRS axis abnormal								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Blood creatine increased								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Body temperature increased								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio abnormal								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio decreased								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio increased								
Europe	1	(0.1)	2	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Weight decreased								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.34
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Amylase increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Antinuclear antibody positive								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood alkaline phosphatase increased								
Europe	0				0			
North America	3	(0.4)	3	0.74	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Blood creatine phosphokinase increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Blood glucose decreased								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood glucose fluctuation								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Blood glucose increased								
Europe	0				2	(0.2)	2	0.34
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood potassium increased								
Europe	0				1	(0.1)	1	0.20
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood pressure decreased								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood testosterone decreased								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Blood uric acid increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Blood urine present								
Europe	0				0			
North America	1	(0.2)	3	0.46	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone density decreased								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Breath sounds abnormal								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Carbohydrate antigen 19-9 increased								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac murmur								
Europe	0				1	(0.1)	1	0.22
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac stress test abnormal								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Catheterisation cardiac								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Ejection fraction decreased								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram abnormal								
Europe	0				0			
North America	2	(0.3)	2	0.43	2	(0.3)	2	0.43
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram P wave biphasic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Electrocardiogram repolarisation abnormality								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram ST segment abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram ST segment depression								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Free fatty acids increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Glomerular filtration rate decreased								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Glycosylated haemoglobin increased								
Europe	0				2	(0.2)	3	0.32
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Grip strength decreased								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematocrit increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemoglobin decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.61
Haemoglobin increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Hepatic enzyme increased								
Europe	0				0			
North America	2	(0.3)	2	0.43	2	(0.3)	2	0.49
South America	0				0			
Africa	0				0			
Asia	0				0			
Intraocular pressure increased								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipase increased								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipids abnormal								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipids increased								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Liver function test abnormal								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	2	0.71
Liver function test increased								
Europe	0				0			
North America	2	(0.3)	2	0.38	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Monocyte count decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.41
Monofilament pressure perception test								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Mycobacterium tuberculosis complex test positive								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Occult blood positive								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Platelet count decreased								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.81
Prostatic specific antigen increased								
Europe	0				0			
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Red blood cell count decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Thyroid function test abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Transaminases increased								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Transferrin saturation decreased								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitamin D decreased								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
White blood cell count decreased								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal and urinary disorders								
All								
Europe	26	(2.8)	35	5.02	19	(2.1)	29	4.08
North America	16	(2.4)	18	3.44	16	(2.3)	21	3.25
South America	1	(0.8)	1	1.32	5	(3.8)	5	5.46
Africa	2	(8.0)	2	13.31	0			
Asia	9	(2.2)	9	3.30	14	(3.1)	15	4.78
Nephrolithiasis								
Europe	4	(0.4)	4	0.41	1	(0.1)	2	0.37
North America	1	(0.2)	1	0.15	2	(0.3)	3	0.43
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Chronic kidney disease								
Europe	3	(0.3)	3	0.52	3	(0.3)	3	0.44
North America	0				1	(0.1)	1	0.14
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Dysuria								
Europe	3	(0.3)	4	0.51	2	(0.2)	2	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	2	(0.5)	2	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Renal pain								
Europe	3	(0.3)	3	0.55	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ureterolithiasis								
Europe	3	(0.3)	3	0.40	0			
North America	0				2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Diabetic nephropathy								
Europe	3	(0.3)	3	0.40	1	(0.1)	1	0.22
North America	0				0			
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Microalbuminuria								
Europe	2	(0.2)	2	0.33	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urine odour abnormal								
Europe	2	(0.2)	2	0.29	0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal cyst								
Europe	2	(0.2)	2	0.21	3	(0.3)	3	0.39
North America	2	(0.3)	2	0.37	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	3	1.23	1	(0.2)	1	0.39
Acute kidney injury								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.11
North America	2	(0.3)	2	0.41	4	(0.6)	4	0.58
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematuria								
Europe	1	(0.1)	2	0.41	3	(0.3)	3	0.42
North America	0				2	(0.3)	2	0.29

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal failure								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Polyuria								
Europe	1	(0.1)	1	0.18	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Calculus urinary								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Pollakiuria								
Europe	1	(0.1)	1	0.11	0			
North America	3	(0.4)	3	0.76	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	2	(0.4)	2	0.45
Pyelocaliectasis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal colic								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.28
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Bladder mass								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bladder prolapse								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chromaturia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Cystitis haemorrhagic								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydrocalyx								
Europe	0				2	(0.2)	2	0.40
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydronephrosis								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Hypertensive nephropathy								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertonic bladder								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Micturition urgency								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Nephropathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Nephrotic syndrome								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Nocturia								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.23
Proteinuria								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal impairment								
Europe	0				1	(0.1)	1	0.12
North America	2	(0.3)	2	0.41	1	(0.1)	1	0.14
South America	0				1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.25	0			
Renal mass								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Strangury								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.2)	1	0.41
Stress urinary incontinence								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urethral stenosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Urinary incontinence								
Europe	0				1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Urinary retention								
Europe	0				1	(0.1)	1	0.12
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract disorder								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract inflammation								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract obstruction								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Europe	15	(1.6)	20	2.66	11	(1.2)	18	2.37
North America	9	(1.3)	12	2.17	12	(1.8)	16	2.80
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	0			
Asia	9	(2.3)	9	3.57	6	(1.3)	9	2.92
Pancreatic neoplasm								
Europe	2	(0.2)	2	0.31	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to liver								
Europe	2	(0.2)	2	0.21	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Seborrhoeic keratosis								
Europe	2	(0.2)	3	0.32	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye naevus								
Europe	1	(0.1)	1	0.20	0			
North America	2	(0.3)	3	0.58	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteoma								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Small cell lung cancer								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bladder papilloma								
Europe	1	(0.1)	1	0.19	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lung cancer metastatic								
Europe	1	(0.1)	1	0.19	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Colon adenoma								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.2)	1	0.41	0			
Colorectal cancer								
Europe	1	(0.1)	1	0.10	0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatic carcinoma								
Europe	1	(0.1)	1	0.10	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal neoplasm								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Basal cell carcinoma								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	0				2	(0.3)	2	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Glioblastoma multiforme								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral fibroma								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Salivary gland neoplasm								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acrochordon								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adenocarcinoma of colon								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Adenocarcinoma pancreas								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Adrenal adenoma								
Europe	0				2	(0.2)	2	0.36
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Benign neoplasm of thyroid gland								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Benign renal neoplasm								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Bladder cancer								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bowen's disease								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Breast cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Breast cancer metastatic								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic myeloid leukaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Colon cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Colon cancer stage II								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysplastic naevus								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Endometrial adenocarcinoma								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastric cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Gastrointestinal tract adenoma								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemangioma of liver								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.80	0			
Hepatocellular carcinoma								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Invasive breast carcinoma								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Invasive ductal breast carcinoma								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Invasive lobular breast carcinoma								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipoma								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lung adenocarcinoma								
Europe	0				1	(0.1)	1	0.19
North America	0				1	(0.2)	1	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Lymphangioma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Malignant melanoma								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malignant melanoma in situ								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malignant peritoneal neoplasm								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Melanocytic naevus								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to bone marrow								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to lymph nodes								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Myxoma								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Neoplasm skin								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Ovarian cancer metastatic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Pancreatic carcinoma metastatic								
Europe	0				0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Prostate cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Prostatic adenoma								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal cell carcinoma								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal hamartoma								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin papilloma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Small intestine neuroendocrine tumour								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Squamous cell carcinoma of skin								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Uterine cancer								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine leiomyoma								
Europe	0				2	(0.2)	2	0.28
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				2	(0.4)	2	0.61
Blood and lymphatic system disorders								
All								
Europe	14	(1.5)	14	2.00	10	(1.1)	10	1.30
North America	10	(1.5)	10	1.83	10	(1.5)	10	2.09
South America	4	(3.1)	4	4.79	6	(4.4)	6	5.59
Africa	1	(4.0)	3	19.96	0			
Asia	7	(1.7)	7	2.54	7	(1.6)	7	2.48
Anaemia								
Europe	8	(0.9)	8	1.15	3	(0.3)	3	0.33
North America	5	(0.8)	5	0.86	4	(0.6)	4	0.84
South America	3	(2.3)	3	3.96	5	(3.7)	5	4.88
Africa	1	(4.0)	3	19.96	0			
Asia	3	(0.7)	3	1.07	2	(0.5)	2	0.63
Lymphadenopathy mediastinal								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Lymphadenitis								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Leukocytosis								
Europe	1	(0.1)	1	0.10	3	(0.3)	3	0.32
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Splenomegaly								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Iron deficiency anaemia								
Europe	1	(0.1)	1	0.11	2	(0.2)	2	0.34
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.40
Polycythaemia								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood loss anaemia								
Europe	0				0			
North America	1	(0.1)	1	0.23	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophilia								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	0.83	1	(0.7)	1	0.72
Africa	0				0			
Asia	1	(0.2)	1	0.41	1	(0.2)	1	0.40
Hypochromic anaemia								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Leukopenia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Lymphadenopathy								
Europe	0				0			
North America	3	(0.4)	3	0.58	1	(0.2)	1	0.34

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Normocytic anaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Pancytopenia								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombocytopenia								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Thrombocytosis								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Psychiatric disorders								
All								
Europe	12	(1.3)	13	1.80	20	(2.2)	21	3.30
North America	18	(2.6)	21	3.80	17	(2.6)	19	4.19
South America	4	(3.1)	4	4.79	1	(0.8)	1	1.43
Africa	0				1	(4.0)	1	6.75
Asia	7	(1.7)	7	2.27	4	(0.9)	4	1.42
Sleep disorder								
Europe	4	(0.4)	4	0.53	1	(0.1)	1	0.20
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.58
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Anxiety								
Europe	3	(0.3)	3	0.44	3	(0.3)	3	0.45
North America	2	(0.3)	2	0.30	7	(1.1)	7	1.57

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Depressed mood								
Europe	2	(0.2)	2	0.33	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Insomnia								
Europe	2	(0.2)	2	0.29	2	(0.2)	3	0.49
North America	2	(0.3)	2	0.49	2	(0.3)	2	0.29
South America	2	(1.6)	2	2.15	0			
Africa	0				0			
Asia	5	(1.2)	5	1.45	2	(0.5)	2	0.63
Depression								
Europe	1	(0.1)	1	0.10	4	(0.5)	4	0.64
North America	7	(1.0)	7	1.21	6	(0.9)	6	1.34
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Listless								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adjustment disorder								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adjustment disorder with depressed mood								
Europe	0				0			
North America	0				1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
Adjustment disorder with mixed anxiety and depressed mood								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Affect lability								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Agitation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Anxiety disorder								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Attention deficit hyperactivity disorder								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bruxism								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Disorientation								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug abuse								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Drug dependence								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Emotional distress								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fear								
Europe	0				2	(0.2)	2	0.35
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Irritability								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Major depression								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Mental status changes								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mixed anxiety and depressive disorder								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mood swings								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Nightmare								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Persistent depressive disorder								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Phobia								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post-traumatic stress disorder								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Stress								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hepatobiliary disorders								
All								
Europe	9	(1.0)	13	1.91	15	(1.7)	15	2.23
North America	1	(0.2)	2	0.31	1	(0.1)	2	0.28
South America	2	(1.7)	3	2.49	1	(0.7)	1	0.72
Africa	0				0			
Asia	12	(3.0)	13	5.19	8	(1.8)	11	3.70
Hepatic steatosis								
Europe	4	(0.4)	4	0.54	5	(0.6)	5	0.65
North America	1	(0.2)	1	0.15	0			
South America	1	(0.8)	1	0.83	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	5	(1.3)	5	2.00	5	(1.1)	5	1.67
Hepatomegaly								
Europe	2	(0.2)	2	0.30	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholelithiasis								
Europe	2	(0.2)	2	0.20	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Cholecystitis chronic								
Europe	1	(0.1)	1	0.20	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gallbladder polyp								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	3	(0.6)	3	1.18
Hypertransaminasaemia								
Europe	1	(0.1)	1	0.23	0			
North America	0				0			
South America	1	(0.8)	2	1.66	0			
Africa	0				0			
Asia	0				0			
Hepatic mass								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gallbladder cholesterolosis								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Alcoholic liver disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Bile duct stone								
Europe	0				0			
North America	0				1	(0.1)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Biliary colic								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Biliary dyskinesia								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholecystitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Gallbladder disorder								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hepatic calcification								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Hepatic cirrhosis								
Europe	0				1	(0.1)	1	0.20
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Hepatic cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Hepatic function abnormal								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	2	(0.5)	2	0.63
Hyperplastic cholecystopathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Liver disorder								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Non-alcoholic steatohepatitis								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nonalcoholic fatty liver disease								
Europe	0				2	(0.2)	2	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Steatohepatitis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Reproductive system and breast disorders								
All								
Europe	9	(1.0)	9	1.18	9	(1.0)	13	2.10
North America	12	(1.7)	12	2.20	10	(1.5)	12	1.86
South America	5	(3.9)	5	6.64	2	(1.5)	2	2.60
Africa	0				1	(4.0)	1	6.75
Asia	7	(1.7)	7	2.31	5	(1.1)	5	1.47
Benign prostatic hyperplasia								
Europe	2	(0.2)	2	0.33	1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	2	(0.3)	2	0.44
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	2	(0.5)	2	0.70	0			
Dysmenorrhoea								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.22
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrophic vulvovaginitis								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Menstruation irregular								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Breast mass								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Erectile dysfunction								
Europe	1	(0.1)	1	0.11	0			
North America	3	(0.4)	3	0.52	0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	1	(0.2)	1	0.25	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Uterine prolapse								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Vulvovaginal pruritus								
Europe	1	(0.1)	1	0.11	0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Breast pain								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Cervical polyp								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Colpocele								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ectropion of cervix								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ejaculation failure								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fibrocystic breast disease								
Europe	0				1	(0.1)	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Galactorrhoea								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Genital prolapse								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Intermenstrual bleeding								
Europe	0				0			
North America	0				0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Menopausal disorder								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.40
Menopausal symptoms								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Menstruation delayed								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Ovarian cyst								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Ovarian disorder								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pelvic discomfort								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Penile pain								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Penile rash								
Europe	0				1	(0.1)	2	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Premenstrual syndrome								
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.39
Prostatic calcification								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.41	0			
Prostatitis								
Europe	0				0			
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Prostatomegaly								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	1	(0.1)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pruritus genital								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	1	(0.2)	1	0.23
Testicular cyst								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine enlargement								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine polyp								
Europe	0				0			
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaginal discharge								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Vaginal haemorrhage								
Europe	0				0			
North America	0				2	(0.3)	2	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Vulvovaginal dryness								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Ear and labyrinth disorders								
All								
Europe	9	(1.0)	9	1.15	12	(1.3)	12	1.79
North America	13	(1.9)	16	2.65	7	(1.1)	8	1.76
South America	1	(0.8)	1	1.32	1	(0.7)	1	0.72
Africa	0				0			
Asia	5	(1.3)	5	2.07	4	(0.9)	4	1.24
Vertigo								
Europe	3	(0.3)	3	0.40	2	(0.2)	2	0.29
North America	4	(0.6)	5	0.83	3	(0.5)	4	0.74
South America	0				0			
Africa	0				0			
Asia	3	(0.7)	3	1.07	4	(0.9)	4	1.24
Ear pain								
Europe	2	(0.2)	2	0.33	1	(0.1)	1	0.20
North America	3	(0.4)	3	0.52	1	(0.2)	1	0.34
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Tinnitus								
Europe	2	(0.2)	2	0.21	2	(0.2)	2	0.31
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoacusis								
Europe	1	(0.1)	1	0.10	3	(0.3)	3	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.45	0			
Ear inflammation								
Europe	1	(0.1)	1	0.11	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerumen impaction								
Europe	0				0			
North America	1	(0.1)	1	0.23	1	(0.2)	1	0.29
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Deafness bilateral								
Europe	0				0			
North America	2	(0.3)	2	0.30	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Deafness neurosensory								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Deafness unilateral								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear discomfort								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eustachian tube dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.26
South America	0				0			
Africa	0				0			
Asia	0				0			
External ear pain								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Meniere's disease								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Middle ear inflammation								
Europe	0				1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Motion sickness								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Presbyacusis								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vertigo positional								
Europe	0				0			
North America	2	(0.3)	2	0.30	0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Immune system disorders								
All								
Europe	4	(0.4)	5	0.75	6	(0.7)	7	1.15
North America	10	(1.4)	10	1.93	8	(1.2)	8	1.74
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Hypersensitivity								
Europe	2	(0.2)	2	0.43	0			
North America	1	(0.1)	1	0.27	0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Seasonal allergy								
Europe	2	(0.2)	2	0.21	3	(0.3)	3	0.53
North America	6	(0.9)	6	1.06	6	(0.9)	6	1.32
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Allergy to arthropod bite								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.19
North America	0				1	(0.2)	1	0.28
South America	0				0			
Africa	0				0			
Asia	0				0			
Allergy to arthropod sting								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Anaphylactic reaction								
Europe	0				1	(0.1)	1	0.20
North America	1	(0.1)	1	0.22	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug hypersensitivity								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Food allergy								
Europe	0				0			
North America	1	(0.2)	1	0.15	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Immunisation reaction								
Europe	0				1	(0.1)	2	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Surgical and medical procedures								
All								
Europe	3	(0.3)	3	0.53	3	(0.3)	3	0.48
North America	2	(0.3)	2	0.38	2	(0.3)	2	0.29
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	1	(0.2)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tooth extraction								
Europe	1	(0.1)	1	0.20	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin neoplasm excision								
Europe	1	(0.1)	1	0.23	1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac pacemaker replacement								
Europe	1	(0.1)	1	0.10	1	(0.1)	1	0.18
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac ablation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.55	0			
Knee operation								
Europe	0				0			
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Large intestinal polypectomy								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Removal of foreign body								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Shoulder operation								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal operation								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Toe amputation								
Europe	0				1	(0.1)	1	0.20
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Endocrine disorders								
All								
Europe	2	(0.2)	2	0.21	9	(1.0)	9	1.09
North America	4	(0.6)	4	0.76	3	(0.5)	3	0.62
South America	0				2	(1.5)	2	2.73
Africa	0				1	(4.0)	1	6.75
Asia	0				4	(0.9)	4	1.21
Autoimmune thyroiditis								
Europe	1	(0.1)	1	0.10	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thyroid mass								
Europe	1	(0.1)	1	0.11	1	(0.1)	1	0.11
North America	1	(0.2)	1	0.15	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Adrenal mass								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adrenocortical insufficiency acute								
Europe	0				1	(0.1)	1	0.20
North America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Goitre								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Hyperplasia adrenal								
Europe	0				1	(0.1)	1	0.12
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperprolactinaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.23
Hyperthyroidism								
Europe	0				2	(0.2)	2	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypogonadism								
Europe	0				0			
North America	1	(0.1)	1	0.23	1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypothyroidism								
Europe	0				2	(0.2)	2	0.22
North America	2	(0.3)	2	0.38	2	(0.3)	2	0.48
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.35
Inappropriate antidiuretic hormone secretion								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Secondary hypogonadism								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Congenital, familial and genetic disorders								
All								
Europe	0				2	(0.2)	2	0.21
North America	2	(0.3)	2	0.48	2	(0.3)	2	0.29
South America	3	(2.4)	3	3.47	1	(0.8)	1	1.30
Africa	0				0			
Asia	1	(0.2)	1	0.25	0			
Atrial septal defect								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Congenital syphilitic osteochondritis								
Europe	0				0			
North America	0				1	(0.1)	1	0.15
South America	0				0			
Africa	0				0			
Asia	0				0			
Corneal dystrophy								
Europe	0				0			
North America	1	(0.1)	1	0.23	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cystic fibrosis lung								
Europe	0				0			
North America	1	(0.1)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydrocele								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.2)	1	0.25	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypertrophic cardiomyopathy								
Europe	0				1	(0.1)	1	0.11
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Myotonic dystrophy								
Europe	0				0			
North America	0				1	(0.1)	1	0.14
South America	0				0			
Africa	0				0			
Asia	0				0			
Type V hyperlipidaemia								
Europe	0				0			
North America	0				0			
South America	3	(2.4)	3	3.47	1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Social circumstances								
All								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Menopause								
Europe	0				1	(0.1)	1	0.19
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.7.36 Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Europe	782				755			
North America	591				576			
South America	128				131			
Africa	25				25			
Asia	354				391			
PYE (years)								
Europe	693.26				663.77			
North America	494.44				493.99			
South America	82.20				85.02			
Africa	15.03				14.82			
Asia	254.00				278.87			
Events								
Europe	443	(56.6)	1424	220.57	412	(54.5)	1266	202.21
North America	384	(64.7)	1193	253.01	347	(60.4)	1065	235.40
South America	83	(65.1)	193	237.97	79	(60.0)	198	233.25
Africa	16	(64.0)	74	492.32	16	(64.0)	42	283.35
Asia	213	(60.2)	594	234.48	219	(56.3)	688	244.96
Infections and infestations								
All								
Europe	239	(30.6)	347	54.11	222	(29.4)	340	52.71
North America	186	(31.1)	264	56.97	174	(30.3)	235	53.71
South America	42	(32.7)	60	75.84	43	(32.4)	66	74.68
Africa	9	(36.0)	14	93.14	5	(20.0)	6	40.48
Asia	68	(19.3)	88	35.34	79	(20.3)	110	38.07
COVID-19								
Europe	73	(9.3)	73	11.29	85	(11.3)	88	13.32
North America	59	(10.1)	62	13.00	56	(9.7)	58	12.30
South America	16	(12.4)	16	20.89	14	(10.4)	14	14.50
Africa	0				2	(8.0)	2	13.49
Asia	4	(1.1)	4	1.75	3	(0.8)	3	0.78
Nasopharyngitis								
Europe	47	(6.0)	59	9.78	39	(5.2)	46	7.80
North America	11	(1.8)	12	2.65	13	(2.3)	15	3.79
South America	4	(3.1)	4	5.32	2	(1.5)	2	2.60
Africa	0				0			
Asia	21	(6.1)	24	9.55	25	(6.4)	29	9.67

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Upper respiratory tract infection								
Europe	25	(3.1)	32	4.01	12	(1.6)	13	1.76
North America	25	(4.1)	30	6.65	21	(3.7)	22	4.86
South America	0				0			
Africa	2	(8.0)	3	19.96	1	(4.0)	1	6.75
Asia	10	(2.7)	10	4.18	11	(2.9)	12	4.92
Urinary tract infection								
Europe	14	(1.8)	14	2.08	9	(1.2)	10	1.39
North America	16	(2.7)	19	4.51	25	(4.3)	27	5.67
South America	3	(2.4)	3	3.47	6	(4.5)	6	6.18
Africa	1	(4.0)	1	6.65	0			
Asia	3	(0.8)	3	1.23	4	(1.0)	5	1.92
Influenza								
Europe	13	(1.7)	13	2.49	11	(1.5)	13	2.42
North America	4	(0.7)	4	0.89	5	(0.9)	5	1.50
South America	11	(8.5)	14	18.52	11	(8.4)	12	15.66
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
COVID-19 pneumonia								
Europe	12	(1.5)	12	2.01	6	(0.8)	6	0.87
North America	2	(0.3)	2	0.44	3	(0.5)	3	0.63
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Bronchitis								
Europe	11	(1.4)	11	1.72	5	(0.7)	5	0.82
North America	10	(1.6)	11	2.37	7	(1.2)	7	1.64
South America	0				0			
Africa	0				0			
Asia	5	(1.4)	5	2.36	5	(1.3)	5	1.71
Respiratory tract infection viral								
Europe	9	(1.2)	10	2.07	8	(1.0)	9	1.74
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastroenteritis								
Europe	9	(1.2)	9	1.64	4	(0.5)	5	0.99
North America	9	(1.5)	9	2.15	5	(0.9)	5	1.50
South America	2	(1.5)	2	2.64	3	(2.2)	3	2.73
Africa	3	(12.0)	3	19.96	1	(4.0)	1	6.75
Asia	3	(0.8)	3	1.23	3	(0.8)	3	0.99

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Respiratory tract infection								
Europe	7	(0.9)	7	1.22	6	(0.8)	6	0.96
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pneumonia								
Europe	7	(0.9)	7	1.15	4	(0.5)	4	0.60
North America	5	(0.8)	5	1.07	1	(0.2)	1	0.30
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.47	1	(0.3)	1	0.47
Pharyngitis								
Europe	7	(0.9)	8	1.12	8	(1.1)	9	1.29
North America	1	(0.2)	2	0.35	0			
South America	6	(4.9)	6	6.00	7	(5.2)	8	8.57
Africa	0				0			
Asia	2	(0.6)	2	0.76	2	(0.5)	3	1.40
Rhinitis								
Europe	6	(0.8)	6	0.76	4	(0.5)	4	0.55
North America	0				1	(0.2)	3	0.99
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.60
Africa	0				0			
Asia	0				0			
Tooth infection								
Europe	4	(0.5)	4	0.60	4	(0.5)	4	0.82
North America	4	(0.7)	6	1.33	3	(0.6)	3	0.83
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Lower respiratory tract infection								
Europe	4	(0.5)	4	0.51	1	(0.1)	3	0.41
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Genital infection								
Europe	3	(0.4)	3	0.46	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cystitis								
Europe	3	(0.4)	3	0.47	9	(1.2)	10	1.66
North America	1	(0.2)	1	0.29	0			
South America	3	(2.3)	3	4.05	1	(0.8)	1	1.43
Africa	0				0			
Asia	5	(1.4)	6	1.95	6	(1.5)	7	2.12
Erysipelas								
Europe	3	(0.4)	3	0.47	0			
North America	0				1	(0.2)	1	0.16
South America	0				1	(0.8)	2	2.60
Africa	0				0			
Asia	0				0			
Viral infection								
Europe	3	(0.4)	3	0.47	7	(0.9)	10	1.38
North America	3	(0.5)	3	0.62	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronavirus infection								
Europe	3	(0.4)	3	0.36	4	(0.5)	6	0.96
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sepsis								
Europe	2	(0.3)	2	0.46	0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Abscess								
Europe	2	(0.3)	2	0.37	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastroenteritis viral								
Europe	2	(0.3)	2	0.37	0			
North America	3	(0.5)	3	0.53	3	(0.5)	3	0.50
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Osteomyelitis								
Europe	2	(0.3)	2	0.37	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tooth abscess								
Europe	2	(0.3)	2	0.37	2	(0.3)	2	0.26
North America	5	(0.8)	5	1.17	5	(0.9)	6	1.53
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal infection								
Europe	2	(0.3)	2	0.43	3	(0.4)	4	0.51
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Otitis media								
Europe	2	(0.3)	2	0.33	1	(0.1)	1	0.14
North America	2	(0.3)	2	0.56	2	(0.4)	2	0.49
South America	0				1	(0.8)	1	1.43
Africa	2	(8.0)	2	13.31	0			
Asia	1	(0.3)	1	0.29	0			
Acarodermatitis								
Europe	2	(0.3)	2	0.24	3	(0.4)	3	0.38
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Conjunctivitis								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.33
North America	3	(0.5)	3	0.62	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	3	(0.9)	3	1.09	4	(1.0)	4	1.45
Fungal infection								
Europe	2	(0.3)	2	0.25	0			
North America	4	(0.7)	5	1.15	2	(0.4)	2	0.51
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Herpes zoster								
Europe	2	(0.3)	2	0.25	6	(0.8)	6	0.89
North America	4	(0.7)	4	0.80	6	(1.0)	7	1.35
South America	1	(0.8)	1	0.83	0			
Africa	0				1	(4.0)	1	6.75
Asia	3	(0.8)	3	1.04	2	(0.5)	2	0.67
Laryngitis								
Europe	2	(0.3)	2	0.25	3	(0.4)	3	0.48
North America	1	(0.2)	1	0.18	0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Tonsillitis								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	1	(0.2)	1	0.41
Sinusitis								
Europe	2	(0.3)	2	0.25	5	(0.7)	7	0.92
North America	12	(2.0)	14	2.99	11	(2.0)	11	2.95
South America	0				1	(0.7)	2	1.43
Africa	0				0			
Asia	0				0			
Vulvovaginal candidiasis								
Europe	2	(0.3)	3	0.38	3	(0.4)	3	0.41
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.3)	1	0.26
Periodontitis								
Europe	1	(0.1)	1	0.24	2	(0.3)	2	0.36
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.04	4	(1.0)	4	1.45
Pneumonia viral								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pulmonary tuberculoma								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral tracheitis								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Onychomycosis								
Europe	1	(0.1)	1	0.21	2	(0.3)	2	0.25
North America	1	(0.2)	1	0.18	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulpitis dental								
Europe	1	(0.1)	1	0.21	1	(0.1)	1	0.21
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				2	(0.5)	2	0.67
Clostridium difficile colitis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear infection fungal								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nail infection								
Europe	1	(0.1)	2	0.24	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peritonsillar abscess								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Vaginal infection								
Europe	1	(0.1)	1	0.12	2	(0.3)	2	0.26
North America	2	(0.3)	2	0.43	1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.95	0			
Asymptomatic COVID-19								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.34
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Balanitis candida								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Candida infection								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Cellulitis								
Europe	1	(0.1)	1	0.13	0			
North America	3	(0.5)	3	0.61	7	(1.2)	8	1.98
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Chlamydial infection								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chronic tonsillitis								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Ear infection								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	2	(0.3)	2	0.43	4	(0.7)	4	0.96
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Gingivitis								
Europe	1	(0.1)	2	0.25	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				3	(0.8)	3	1.34
Helicobacter gastritis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Herpes simplex								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Herpes virus infection								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hordeolum								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	3	(0.5)	3	0.77
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Infected bite								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Laryngopharyngitis								
Europe	1	(0.1)	1	0.13	1	(0.1)	2	0.25
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oropharyngeal candidiasis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Otitis media chronic								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea infection								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Tracheitis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urethritis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Abdominal abscess								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Abscess limb								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Acute sinusitis								
Europe	0				0			
North America	4	(0.7)	4	0.71	2	(0.3)	2	0.33
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Anal abscess								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Appendicitis								
Europe	0				1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bacteraemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Bacterial infection								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bartholinitis								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Body tinea								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Breast abscess								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Breast cellulitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Campylobacter gastroenteritis								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholecystitis infective								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Chronic hepatitis C								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chronic sinusitis								
Europe	0				2	(0.3)	2	0.27
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Clostridium difficile infection								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Dermatophytosis of nail								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26
Diabetic foot infection								
Europe	0				0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Diverticulitis								
Europe	0				3	(0.4)	3	0.40
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Empyema								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Endophthalmitis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Enteritis infectious								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Epididymitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Escherichia bacteraemia								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Escherichia urinary tract infection								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye infection								
Europe	0				1	(0.1)	1	0.21
North America	0				2	(0.4)	2	0.67
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye infection bacterial								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Folliculitis								
Europe	0				1	(0.1)	1	0.23
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Fungal balanitis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fungal skin infection								
Europe	0				1	(0.1)	1	0.21
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Furuncle								
Europe	0				1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.18
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	1	(0.3)	2	0.57	0			
Gangrene								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastroenteritis norovirus								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Genital candidiasis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Genital infection fungal								
Europe	0				2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Giardiasis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Helicobacter infection								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	1	(0.3)	1	0.26
Herpes dermatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Herpes zoster infection neurological								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Infected dermal cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Infective iritis								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site abscess								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Kidney infection								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Labyrinthitis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Localised infection								
Europe	0				1	(0.1)	1	0.13
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Lyme disease								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mastitis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oophoritis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral candidiasis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Oral herpes								
Europe	0				0			
North America	2	(0.3)	3	0.83	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Otitis externa								
Europe	0				2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Otitis media acute								
Europe	0				2	(0.3)	2	0.26
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Paraspinal abscess								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Paronychia								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	1	(0.3)	2	0.93
Parotitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Peri-implantitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pericoronitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Pharyngotonsillitis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.36	2	(1.4)	3	2.15
Africa	0				0			
Asia	0				0			
Post procedural infection								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Post-acute COVID-19 syndrome								
Europe	0				0			
North America	1	(0.2)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Postoperative wound infection								
Europe	0				0			
North America	1	(0.2)	1	0.29	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Purulence								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Pustule								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pyelonephritis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Respiratory syncytial virus infection								
Europe	0				0			
North America	3	(0.5)	3	0.62	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rotavirus infection								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Salpingitis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinusitis bacterial								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin bacterial infection								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin candida								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Skin infection								
Europe	0				1	(0.1)	1	0.22
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Soft tissue infection								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Subcutaneous abscess								
Europe	0				0			
North America	2	(0.3)	2	0.43	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	2	0.52
Suspected COVID-19								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sweat gland infection								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea cruris								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tinea pedis								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tinea versicolour								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urosepsis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Varicella								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Varicella zoster virus infection								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral pharyngitis								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral rhinitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Viral upper respiratory tract infection								
Europe	0				2	(0.3)	2	0.27
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vulvitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Vulvovaginal mycotic infection								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	0				0			
Wound infection								
Europe	0				0			
North America	3	(0.5)	3	0.72	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal disorders								
All								
Europe	103	(13.1)	163	25.10	73	(9.7)	100	15.92
North America	84	(14.2)	118	24.50	76	(13.3)	101	23.05
South America	10	(7.9)	12	14.41	15	(11.5)	22	27.25
Africa	5	(20.0)	10	66.53	3	(12.0)	3	20.24
Asia	49	(13.9)	77	29.97	54	(13.9)	76	27.27
Diarrhoea								
Europe	27	(3.4)	35	5.15	17	(2.3)	17	2.80
North America	31	(5.2)	37	7.86	17	(3.0)	17	4.02
South America	6	(4.8)	6	6.45	5	(3.9)	5	6.63
Africa	3	(12.0)	3	19.96	2	(8.0)	2	13.49
Asia	17	(4.8)	21	8.66	10	(2.6)	11	3.84
Nausea								
Europe	11	(1.4)	12	1.93	9	(1.2)	10	1.69
North America	14	(2.4)	14	2.75	14	(2.5)	15	3.35
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	11	(3.1)	11	4.17	3	(0.8)	3	1.13
Abdominal pain								
Europe	9	(1.2)	9	1.55	5	(0.7)	5	0.92
North America	6	(1.0)	6	1.14	10	(1.7)	11	2.49
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.43
Africa	0				0			
Asia	0				2	(0.5)	2	0.73

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Abdominal pain upper								
Europe	9	(1.1)	11	1.73	8	(1.1)	9	1.37
North America	3	(0.5)	3	0.65	4	(0.7)	4	1.01
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				3	(0.7)	3	0.93
Gastrooesophageal reflux disease								
Europe	7	(0.9)	7	0.96	4	(0.5)	4	0.53
North America	4	(0.7)	4	0.80	2	(0.4)	2	0.49
South America	0				3	(2.3)	3	3.32
Africa	0				0			
Asia	2	(0.6)	2	1.00	5	(1.3)	5	1.86
Toothache								
Europe	7	(0.9)	7	0.87	3	(0.4)	5	1.04
North America	1	(0.2)	1	0.27	3	(0.6)	3	0.83
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	5	(1.4)	5	1.67	3	(0.8)	4	1.87
Vomiting								
Europe	6	(0.8)	7	1.39	6	(0.8)	8	1.17
North America	11	(1.8)	16	3.69	6	(1.1)	6	1.52
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.30
Africa	2	(8.0)	2	13.31	0			
Asia	4	(1.1)	6	2.45	3	(0.7)	4	1.19
Dental caries								
Europe	6	(0.8)	7	0.85	3	(0.4)	3	0.38
North America	1	(0.2)	2	0.35	2	(0.4)	2	0.51
South America	0				0			
Africa	0				0			
Asia	4	(1.1)	4	1.14	5	(1.3)	5	2.21
Chronic gastritis								
Europe	5	(0.7)	5	0.85	2	(0.3)	2	0.34
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.6)	2	0.81	2	(0.5)	2	0.52
Gastritis								
Europe	5	(0.6)	5	0.80	3	(0.4)	3	0.47
North America	0				3	(0.5)	3	0.49
South America	0				1	(0.8)	1	1.30
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.47
Constipation								
Europe	4	(0.5)	7	1.43	3	(0.4)	3	0.56

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	8	(1.4)	8	1.51	4	(0.7)	4	0.68
South America	1	(0.8)	1	1.32	3	(2.3)	3	3.91
Africa	0				0			
Asia	3	(0.9)	3	1.33	6	(1.6)	6	2.39
Flatulence								
Europe	4	(0.5)	4	0.69	0			
North America	0				2	(0.3)	2	0.61
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemorrhoids								
Europe	4	(0.5)	4	0.50	2	(0.3)	2	0.37
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.33
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.48	0			
Dyspepsia								
Europe	3	(0.4)	3	0.55	2	(0.3)	2	0.27
North America	2	(0.4)	2	0.35	3	(0.5)	3	0.49
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.6)	2	1.00	2	(0.5)	2	0.87
Diverticulum intestinal								
Europe	3	(0.4)	3	0.36	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Large intestine polyp								
Europe	3	(0.4)	3	0.36	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.25	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				3	(0.7)	4	1.19
Hypoaesthesia oral								
Europe	2	(0.3)	4	0.84	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Abdominal pain lower								
Europe	2	(0.3)	2	0.43	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26
Aphthous ulcer								
Europe	2	(0.3)	2	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rectal polyp								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Abdominal distension								
Europe	2	(0.3)	2	0.25	0			
North America	4	(0.7)	4	0.83	4	(0.7)	4	1.02
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Enterocolitis								
Europe	2	(0.3)	3	0.38	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Pancreatitis chronic								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral pain								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vomiting projectile								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gingival bleeding								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic gastropathy								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophilic oesophagitis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eructation								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal haemorrhage								
Europe	1	(0.1)	1	0.12	2	(0.3)	2	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hiatus hernia								
Europe	1	(0.1)	1	0.12	0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Inguinal hernia								
Europe	1	(0.1)	1	0.12	1	(0.1)	2	0.27
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lip swelling								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Umbilical hernia								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Colitis								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Dry mouth								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Food poisoning								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	4	(0.7)	4	0.90	3	(0.6)	4	1.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Frequent bowel movements								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Loose tooth								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatitis								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tooth disorder								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Abdominal discomfort								
Europe	0				0			
North America	0				2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.04	3	(0.8)	4	1.66
Abdominal wall disorder								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acid peptic disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.52
Anal fissure								
Europe	0				0			
North America	1	(0.2)	1	0.18	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Anal pruritus								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Colitis ischaemic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Colitis microscopic								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Crohn's disease								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diverticulum								
Europe	0				1	(0.1)	1	0.22
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.3)	1	0.26
Duodenitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Enteritis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Epigastric discomfort								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Faeces pale								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastric dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastric disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Gastric dysplasia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Gastric mucosal hypertrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Gastric polyps								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.76	2	(0.5)	2	0.67
Gastric ulcer								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal angiodysplasia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Gastrointestinal disorder								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal inflammation								
Europe	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastrointestinal sounds abnormal								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gingival disorder								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematochezia								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemorrhoidal haemorrhage								
Europe	0				1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperaesthesia teeth								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Hyperchlorhydria								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Ileus								
Europe	0				1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Impaired gastric emptying								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intestinal dilatation								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intra-abdominal haematoma								
Europe	0				0			
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Irritable bowel syndrome								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Melaena								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Mesenteric panniculitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Noninfective gingivitis								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Odynophagia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Oesophageal pain								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Oesophagitis								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Oral discomfort								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Pancreatic duct dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Pancreatic failure								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatic pseudocyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Pancreatitis acute								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Peptic ulcer								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Periodontal disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	2	(0.5)	2	0.87
Periodontal inflammation								
Europe	0				1	(0.1)	2	0.27
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Proctalgia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Rectal prolapse								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Small intestinal obstruction								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Stomatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.52

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tongue rough								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Tooth impacted								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.47
Ulcerative gastritis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper gastrointestinal haemorrhage								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Musculoskeletal and connective tissue disorders								
All								
Europe	95	(12.1)	150	22.83	96	(12.7)	141	22.87
North America	85	(14.3)	129	26.82	88	(15.3)	121	27.00
South America	14	(10.9)	23	27.01	11	(8.4)	11	13.52
Africa	5	(20.0)	6	39.92	5	(20.0)	6	40.48
Asia	47	(13.3)	61	24.02	45	(11.7)	59	21.46
Back pain								
Europe	29	(3.7)	32	5.13	24	(3.2)	26	4.37
North America	15	(2.6)	16	3.34	23	(4.1)	24	5.97
South America	2	(1.5)	2	2.64	2	(1.5)	2	2.60
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	15	(4.2)	15	5.41	11	(2.9)	11	4.04
Arthralgia								
Europe	14	(1.8)	16	2.40	19	(2.5)	23	4.00
North America	19	(3.2)	23	5.18	16	(2.8)	18	3.99
South America	2	(1.6)	4	4.30	1	(0.8)	1	1.30
Africa	0				2	(8.0)	2	13.49
Asia	10	(2.9)	10	3.33	10	(2.6)	10	3.78

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Muscle spasms								
Europe	12	(1.5)	12	2.04	2	(0.3)	2	0.27
North America	6	(1.0)	6	1.15	3	(0.5)	3	0.67
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	4	(1.2)	6	3.08	4	(1.0)	4	1.39
Osteoarthritis								
Europe	10	(1.3)	11	1.71	16	(2.1)	18	2.68
North America	6	(1.0)	6	1.24	5	(0.9)	6	1.69
South America	4	(3.2)	5	5.17	2	(1.5)	2	2.02
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.47
Neck pain								
Europe	9	(1.1)	9	1.33	4	(0.5)	4	0.55
North America	3	(0.5)	3	0.79	2	(0.4)	2	0.51
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.6)	2	0.76	2	(0.5)	2	0.73
Pain in extremity								
Europe	8	(1.0)	9	1.13	8	(1.1)	10	1.62
North America	19	(3.3)	20	4.02	15	(2.6)	18	4.22
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.73
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.6)	2	0.57	6	(1.6)	7	3.00
Tendonitis								
Europe	5	(0.6)	7	1.22	2	(0.3)	2	0.36
North America	3	(0.5)	3	0.53	2	(0.4)	2	0.51
South America	0				0			
Africa	0				0			
Asia	0				0			
Myalgia								
Europe	4	(0.5)	4	0.76	2	(0.3)	2	0.45
North America	6	(1.0)	6	1.15	4	(0.7)	4	0.68
South America	3	(2.3)	3	4.00	1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.3)	1	0.52	2	(0.5)	2	0.87
Periarthritis								
Europe	3	(0.4)	3	0.49	2	(0.3)	2	0.27
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	4	(1.2)	4	1.38	3	(0.8)	3	0.99
Osteochondrosis								
Europe	2	(0.3)	2	0.36	4	(0.5)	4	0.68

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Back disorder								
Europe	2	(0.3)	2	0.37	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Musculoskeletal pain								
Europe	2	(0.3)	2	0.35	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc disorder								
Europe	2	(0.3)	2	0.34	2	(0.3)	2	0.36
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chondropathy								
Europe	2	(0.3)	2	0.25	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc protrusion								
Europe	2	(0.3)	6	0.73	1	(0.1)	2	0.27
North America	3	(0.5)	3	0.53	2	(0.3)	2	0.34
South America	0				1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.6)	2	0.76	2	(0.5)	2	0.93
Spinal osteoarthritis								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.26
North America	3	(0.5)	3	0.62	3	(0.5)	4	0.66
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Fibromyalgia								
Europe	2	(0.3)	2	0.25	0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Musculoskeletal chest pain								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Rotator cuff syndrome								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.27	3	(0.5)	3	0.49
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.81	0			
Joint effusion								
Europe	1	(0.1)	2	0.44	0			
North America	1	(0.2)	1	0.18	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal stenosis								
Europe	1	(0.1)	2	0.43	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	3	1.33	0			
Acquired claw toe								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bursitis								
Europe	1	(0.1)	1	0.12	2	(0.3)	2	0.27
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.18
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Diastasis recti abdominis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Foot deformity								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	2	0.24	2	(0.3)	2	0.43
North America	2	(0.3)	3	0.62	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Meniscopathy								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Psoriatic arthropathy								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tendon disorder								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.21
North America	0				0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Arthritis								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.57
North America	4	(0.7)	4	0.78	2	(0.4)	2	0.67
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.26
Costochondritis								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Exostosis								
Europe	1	(0.1)	1	0.13	0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Groin pain								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Musculoskeletal stiffness								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	2	(0.6)	2	0.81	1	(0.3)	1	0.26
Myositis								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteopenia								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Plantar fasciitis								
Europe	1	(0.1)	2	0.25	1	(0.1)	1	0.13
North America	3	(0.5)	3	0.61	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Polyarthritis								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal pain								
Europe	1	(0.1)	1	0.13	4	(0.5)	4	0.63
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthropathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Axillary mass								
Europe	0				0			
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone cyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Bone pain								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical spinal stenosis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Coccydynia								
Europe	0				0			
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Dupuytren's contracture								
Europe	0				1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Facet joint syndrome								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fistula								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Flank pain								
Europe	0				0			
North America	1	(0.2)	1	0.25	4	(0.7)	5	1.17
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.73
Haemarthrosis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Intervertebral disc degeneration								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Intervertebral disc space narrowing								
Europe	0				0			
North America	0				1	(0.2)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Jaw disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Joint swelling								
Europe	0				1	(0.1)	1	0.14
North America	0				2	(0.3)	2	0.61
South America	0				0			
Africa	0				0			
Asia	0				0			
Limb deformity								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Lumbar spinal stenosis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Mastication disorder								
Europe	0				0			
North America	0				1	(0.2)	2	0.35
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscle contracture								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Muscle twitching								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscular weakness								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Neuropathic arthropathy								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nodal osteoarthritis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteochondritis								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Osteoporosis								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Pain in jaw								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Periostitis								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Polymyalgia rheumatica								
Europe	0				1	(0.1)	3	0.69
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Rheumatoid arthritis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Sacroiliitis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Scoliosis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Soft tissue swelling								
Europe	0				0			
North America	1	(0.2)	3	0.76	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal retrolisthesis								
Europe	0				0			
North America	0				1	(0.2)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Synovial cyst								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Tenosynovitis								
Europe	0				3	(0.4)	3	0.39
North America	0				0			
South America	1	(0.8)	1	0.83	0			
Africa	0				1	(4.0)	1	6.75
Asia	0				5	(1.3)	6	1.77
Tenosynovitis stenosans								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Torticollis								
Europe	0				1	(0.1)	1	0.21
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Trigger finger								
Europe	0				2	(0.3)	2	0.25
North America	4	(0.7)	4	0.89	1	(0.2)	1	0.18
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	3	(0.9)	3	1.46	1	(0.3)	3	0.78
Vertebral osteophyte								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nervous system disorders								
All								
Europe	71	(9.0)	103	16.40	66	(8.7)	86	14.90
North America	61	(10.4)	81	16.73	67	(11.6)	90	19.73
South America	13	(10.0)	18	24.11	10	(7.6)	13	16.37
Africa	5	(20.0)	9	59.88	3	(12.0)	4	26.99
Asia	30	(8.4)	41	16.16	37	(9.5)	55	19.77
Headache								
Europe	21	(2.7)	27	4.70	12	(1.6)	13	2.16
North America	15	(2.5)	19	4.11	21	(3.6)	22	4.95
South America	5	(3.9)	6	7.96	4	(3.1)	6	8.31
Africa	3	(12.0)	5	33.27	3	(12.0)	4	26.99
Asia	13	(3.6)	16	6.11	14	(3.6)	22	6.99
Dizziness								
Europe	13	(1.7)	18	2.75	15	(2.0)	20	3.63
North America	15	(2.6)	15	2.92	10	(1.8)	12	2.97
South America	3	(2.3)	6	8.14	1	(0.8)	1	1.30
Africa	1	(4.0)	2	13.31	0			
Asia	6	(1.7)	7	2.93	11	(2.8)	11	3.92
Sciatica								
Europe	5	(0.6)	5	0.91	8	(1.1)	8	1.35
North America	4	(0.7)	4	0.83	4	(0.7)	5	0.98
South America	0				0			
Africa	0				0			
Asia	4	(1.1)	4	1.71	0			
Carpal tunnel syndrome								
Europe	5	(0.6)	5	0.74	2	(0.2)	2	0.42
North America	4	(0.7)	4	0.78	4	(0.7)	4	0.85
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Syncope								
Europe	5	(0.6)	5	0.72	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tremor								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	4	(0.5)	4	0.49	2	(0.3)	2	0.36
North America	4	(0.7)	5	1.00	2	(0.3)	2	0.47
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.04	4	(1.0)	8	3.61
Diabetic neuropathy								
Europe	3	(0.4)	3	0.49	3	(0.4)	3	0.54
North America	0				5	(0.8)	5	0.98
South America	2	(1.5)	2	2.68	2	(1.5)	2	2.02
Africa	0				0			
Asia	0				2	(0.5)	2	0.87
Paraesthesia								
Europe	3	(0.4)	3	0.47	3	(0.4)	3	0.56
North America	5	(0.9)	6	1.06	5	(0.8)	5	0.98
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Cerebrovascular disorder								
Europe	2	(0.3)	2	0.37	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysgeusia								
Europe	2	(0.3)	2	0.37	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Memory impairment								
Europe	2	(0.3)	2	0.37	0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoaesthesia								
Europe	2	(0.3)	2	0.35	3	(0.4)	3	0.66
North America	4	(0.7)	6	1.18	3	(0.5)	4	0.68
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	4	1.71	3	(0.8)	3	0.99
Carotid artery stenosis								
Europe	2	(0.3)	2	0.24	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Migraine								
Europe	2	(0.3)	2	0.25	0			
North America	2	(0.3)	2	0.43	3	(0.5)	3	0.82
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Cerebral arteriosclerosis								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vascular encephalopathy								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Autonomic nervous system imbalance								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervicobrachial syndrome								
Europe	1	(0.1)	1	0.21	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Neuralgia								
Europe	1	(0.1)	1	0.21	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Somnolence								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Amnesia								
Europe	1	(0.1)	1	0.12	0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebral atrophy								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cognitive disorder								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Disturbance in attention								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intracranial pressure increased								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Balance disorder								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Burning sensation								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.23
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26
Cerebral haemorrhage								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical radiculopathy								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dizziness postural								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Neuropathy peripheral								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.45
North America	5	(0.8)	6	1.50	7	(1.2)	7	1.31
South America	0				0			
Africa	0				0			
Asia	0				0			
Post herpetic neuralgia								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Presyncope								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.40
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Transient ischaemic attack								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.48
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Trigeminal neuralgia								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ageusia								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Anosmia								
Europe	0				1	(0.1)	1	0.21
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Basilar migraine								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Brain injury								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Carotid arteriosclerosis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Carotid artery aneurysm								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebral artery embolism								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebral infarction								
Europe	0				1	(0.1)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cerebrovascular accident								
Europe	0				1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Cluster headache								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dementia Alzheimer's type								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Essential tremor								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial nerve disorder								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial paralysis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Hemiparesis								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Hypoglycaemic coma								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyporeflexia								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ischaemic stroke								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lethargy								
Europe	0				0			
North America	0				2	(0.3)	2	0.35
South America	0				0			
Africa	0				0			
Asia	0				0			
Loss of consciousness								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lumbar radiculopathy								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	2	(0.3)	3	0.50
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Mental impairment								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Meralgia paraesthetica								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Morton's neuralgia								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Myelopathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Neuroglycopenia								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	3	0.53
South America	0				0			
Africa	0				0			
Asia	0				0			
Ophthalmic migraine								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Orthostatic tremor								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Parkinsonian gait								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Peripheral paralysis								
Europe	0				0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Piriformis syndrome								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Radiculopathy								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Restless legs syndrome								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Sleep deficit								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Tension headache								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	3	0.86	0			
Thalamic infarction								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombotic stroke								
Europe	0				2	(0.3)	2	0.37
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vascular headache								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Vertebral artery occlusion								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
White matter lesion								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injury, poisoning and procedural complications								
All								
Europe	60	(7.6)	68	10.03	48	(6.3)	54	8.75
North America	57	(9.5)	76	16.61	48	(8.5)	59	14.07
South America	10	(7.9)	13	15.73	11	(8.5)	14	18.72
Africa	5	(20.0)	9	59.88	2	(8.0)	2	13.49
Asia	32	(9.1)	38	14.24	38	(9.7)	49	17.64
Vaccination complication								
Europe	7	(0.9)	7	1.07	9	(1.2)	12	1.93
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.18
South America	0				0			
Africa	1	(4.0)	4	26.61	0			
Asia	6	(1.7)	7	2.48	11	(2.8)	14	4.29
Contusion								
Europe	5	(0.6)	6	0.74	1	(0.1)	1	0.14
North America	3	(0.5)	3	0.61	1	(0.2)	1	0.16
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	5	(1.4)	5	2.03	5	(1.3)	5	1.51
Hand fracture								
Europe	4	(0.5)	4	0.68	0			
North America	1	(0.2)	1	0.29	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Accidental overdose								
Europe	3	(0.4)	3	0.49	1	(0.1)	1	0.22
North America	3	(0.5)	3	0.76	1	(0.2)	1	0.34
South America	0				1	(0.8)	2	2.85
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Fall								
Europe	3	(0.4)	3	0.46	2	(0.3)	3	0.47
North America	14	(2.4)	14	2.80	7	(1.2)	7	1.49
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.81	1	(0.3)	1	0.47
Skin laceration								
Europe	3	(0.4)	3	0.37	0			
North America	3	(0.5)	3	0.70	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Road traffic accident								
Europe	2	(0.3)	2	0.34	0			
North America	2	(0.3)	2	0.43	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Rib fracture								
Europe	2	(0.3)	2	0.35	1	(0.1)	1	0.13
North America	2	(0.3)	2	0.43	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Wound								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.36
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	2	(0.5)	2	0.87
Accidental underdose								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthropod bite								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.13

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	2	(0.3)	2	0.52	2	(0.4)	2	0.67
South America	0				0			
Africa	0				0			
Asia	0				0			
Extra dose administered								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Incorrect dose administered								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.13
North America	2	(0.3)	2	0.53	2	(0.4)	3	0.98
South America	0				2	(1.5)	3	3.91
Africa	0				0			
Asia	0				0			
Procedural complication								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thermal burn								
Europe	1	(0.1)	1	0.22	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	1	(0.3)	1	0.26
Craniocerebral injury								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Subcutaneous haematoma								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Femoral neck fracture								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Foot fracture								
Europe	1	(0.1)	1	0.12	0			
North America	2	(0.3)	2	0.53	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.67
Hip fracture								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Inflammation of wound								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injury of conjunctiva								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Multiple injuries								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Penile contusion								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural complication								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural inflammation								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Procedural pain								
Europe	1	(0.1)	1	0.12	0			
North America	2	(0.3)	2	0.59	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Tendon rupture								
Europe	1	(0.1)	1	0.12	0			
North America	1	(0.2)	1	0.29	1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper limb fracture								
Europe	1	(0.1)	1	0.12	0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ankle fracture								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	3	(0.5)	3	0.53	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Cervical vertebral fracture								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye injury								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fibula fracture								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	1	(0.8)	1	0.83	0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Injury								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Joint injury								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.27	2	(0.3)	2	0.34
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.29	0			
Ligament sprain								
Europe	1	(0.1)	1	0.13	4	(0.5)	4	0.78
North America	4	(0.7)	4	0.90	1	(0.2)	1	0.16
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	3	(0.9)	3	1.28	3	(0.8)	3	1.19
Limb injury								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.54
North America	1	(0.2)	1	0.18	2	(0.4)	3	0.82
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.6)	2	0.76	0			
Meniscus injury								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.25
North America	0				2	(0.3)	2	0.33
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Post procedural fistula								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural haemorrhage								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Post procedural hypothyroidism								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Radius fracture								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Skin abrasion								
Europe	1	(0.1)	1	0.13	0			
North America	3	(0.5)	5	1.08	2	(0.4)	2	0.49
South America	0				0			
Africa	0				0			
Asia	4	(1.1)	4	1.56	2	(0.5)	2	0.93
Tooth fracture								
Europe	1	(0.1)	1	0.13	0			
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.18
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Traumatic haematoma								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Animal bite								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.73
Arthropod sting								
Europe	0				0			
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Back injury								
Europe	0				0			
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.16

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone contusion								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Burn oral cavity								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Burns first degree								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Chillblains								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	1	(0.3)	1	0.26
Concussion								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Crush injury								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Deafness traumatic								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Endotracheal intubation complication								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Epicondylitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Exposure to SARS-CoV-2								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Face injury								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial bones fracture								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gun shot wound								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Head injury								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Heat illness								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	3	(0.7)	4	1.19
Humerus fracture								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Intentional overdose								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Intentional product use issue								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Ligament rupture								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Lower limb fracture								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medication error								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Muscle contusion								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.2)	1	0.41
Muscle injury								
Europe	0				2	(0.3)	2	0.44
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Muscle strain								
Europe	0				3	(0.4)	3	0.56
North America	0				1	(0.2)	1	0.16
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Neck injury								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Overdose								
Europe	0				1	(0.1)	1	0.21
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				1	(0.8)	1	1.30
Africa	2	(8.0)	2	13.31	0			
Asia	1	(0.3)	1	0.47	0			
Periprocedural myocardial infarction								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural haematuria								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural stroke								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Post procedural swelling								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	2	0.27
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post-traumatic neck syndrome								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Product administration error								
Europe	0				1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Radiation skin injury								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Scar								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Scratch								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Seroma								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Soft tissue injury								
Europe	0				2	(0.3)	2	0.26
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Spinal column injury								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal compression fracture								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Stab wound								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Subdural haematoma								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sunburn								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tendon injury								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Tibia fracture								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Underdose								
Europe	0				0			
North America	0				4	(0.7)	4	1.16
South America	0				1	(0.8)	1	1.30
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Wrist fracture								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Wrong dose								
Europe	0				0			
North America	0				0			
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				0			
Wrong product administered								
Europe	0				0			
North America	1	(0.2)	2	0.53	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
General disorders and administration site conditions								
All								
Europe	57	(7.3)	81	13.09	55	(7.3)	74	12.31
North America	80	(13.6)	131	29.55	59	(10.2)	97	19.76
South America	7	(5.5)	8	10.11	4	(3.0)	5	5.46
Africa	4	(16.0)	6	39.92	1	(4.0)	1	6.75
Asia	51	(14.4)	87	35.15	55	(14.1)	84	28.14
Pyrexia								
Europe	8	(1.0)	8	1.10	8	(1.1)	8	1.61
North America	7	(1.2)	7	1.56	6	(1.0)	6	1.33
South America	0				1	(0.8)	1	1.43
Africa	1	(4.0)	1	6.65	0			
Asia	16	(4.6)	17	6.41	22	(5.6)	24	7.37
Fatigue								
Europe	7	(0.9)	8	1.38	3	(0.4)	3	0.49
North America	18	(3.1)	20	4.11	11	(1.9)	11	2.19
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.29	1	(0.2)	1	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asthenia								
Europe	6	(0.8)	6	1.03	4	(0.5)	4	0.64
North America	0				1	(0.2)	1	0.34
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	3	(0.8)	3	1.04	3	(0.8)	3	0.99
Chest pain								
Europe	4	(0.5)	4	0.49	2	(0.3)	2	0.26
North America	7	(1.2)	7	1.42	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.47	1	(0.3)	1	0.26
Injection site reaction								
Europe	3	(0.4)	4	0.78	0			
North America	6	(1.0)	19	5.40	5	(0.9)	7	1.59
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	4	(1.1)	4	1.89	1	(0.3)	1	0.26
Drug intolerance								
Europe	3	(0.4)	3	0.37	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site haematoma								
Europe	2	(0.3)	6	1.32	3	(0.4)	8	1.76
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Influenza like illness								
Europe	2	(0.3)	3	0.46	3	(0.4)	3	0.39
North America	1	(0.2)	1	0.25	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Discomfort								
Europe	2	(0.3)	2	0.35	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	8	3.73
Oedema peripheral								
Europe	2	(0.3)	2	0.35	3	(0.4)	3	0.48

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	11	(1.9)	11	2.23	5	(0.9)	6	1.19
South America	1	(0.8)	1	1.32	1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.5)	2	0.94	0			
Hunger								
Europe	2	(0.3)	3	0.47	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	4	(1.1)	4	1.14	2	(0.5)	2	0.67
Medical device site dermatitis								
Europe	2	(0.3)	2	0.34	0			
North America	1	(0.2)	4	0.71	1	(0.2)	1	0.18
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	1	(0.3)	1	0.47	6	(1.5)	12	3.13
Medical device site reaction								
Europe	2	(0.3)	4	0.59	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Vaccination site pain								
Europe	2	(0.3)	3	0.47	2	(0.3)	2	0.27
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	8	(2.3)	9	3.83	5	(1.2)	5	2.16
Gait disturbance								
Europe	2	(0.3)	2	0.25	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site bruise								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.14
North America	3	(0.5)	5	1.04	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Feeling abnormal								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.3)	3	0.86	1	(0.3)	1	0.26
Multiple organ dysfunction syndrome								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pain								
Europe	1	(0.1)	1	0.24	3	(0.4)	3	0.48
North America	7	(1.2)	8	1.81	8	(1.4)	8	1.62
South America	0				1	(0.8)	2	2.60
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.52	1	(0.3)	1	0.26
Inflammation								
Europe	1	(0.1)	1	0.22	2	(0.3)	2	0.26
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site pain								
Europe	1	(0.1)	1	0.22	5	(0.6)	5	1.00
North America	1	(0.2)	1	0.29	6	(1.0)	24	4.24
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.47
Chills								
Europe	1	(0.1)	1	0.21	0			
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Medical device site erythema								
Europe	1	(0.1)	1	0.21	2	(0.3)	2	0.34
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Localised oedema								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Swelling face								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.12	0			
North America	0				2	(0.3)	2	0.47
South America	0				0			
Africa	0				0			
Asia	0				0			
Chest discomfort								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.36
North America	4	(0.7)	4	0.90	0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	2	(0.6)	2	0.76	0			
Feeling hot								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site hypersensitivity								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malaise								
Europe	1	(0.1)	1	0.13	4	(0.5)	6	1.01
North America	4	(0.7)	5	0.88	1	(0.2)	1	0.16
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	7	(2.0)	8	2.89	7	(1.8)	9	2.90
Medical device site eczema								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Medical device site haemorrhage								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.57	2	(0.5)	2	0.52
Medical device site pruritus								
Europe	1	(0.1)	1	0.13	0			
North America	3	(0.5)	3	0.61	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Peripheral swelling								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.26
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	3	1.24	2	(0.5)	2	0.93
Swelling								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Thirst								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.22
North America	2	(0.3)	2	0.56	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Application site bruise								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Application site pruritus								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Axillary pain								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Condition aggravated								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cyst								
Europe	0				0			
North America	0				2	(0.4)	2	0.50
South America	0				0			
Africa	0				0			
Asia	0				0			
Death								
Europe	0				2	(0.3)	2	0.26
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Early satiety								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Facial pain								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Hernia								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Implant site pruritus								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site bruising								
Europe	0				1	(0.1)	1	0.14
North America	3	(0.5)	3	0.76	4	(0.7)	4	0.81
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site dermatitis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site erythema								
Europe	0				2	(0.3)	2	0.27
North America	2	(0.3)	4	1.18	1	(0.2)	1	0.18
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Injection site haemorrhage								
Europe	0				0			
North America	1	(0.2)	1	0.29	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.26
Injection site hypertrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Injection site induration								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Injection site mass								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site oedema								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site pruritus								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	17	8.08	1	(0.3)	1	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injection site rash								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Injection site swelling								
Europe	0				0			
North America	2	(0.3)	2	0.55	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Injection site urticaria								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site haematoma								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site hypersensitivity								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Medical device site inflammation								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site pain								
Europe	0				2	(0.3)	2	0.34
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Medical device site rash								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Non-cardiac chest pain								
Europe	0				2	(0.3)	4	0.51
North America	0				2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Oedema								
Europe	0				0			
North America	1	(0.2)	1	0.27	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Oedema due to renal disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Procedural failure								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Systemic inflammatory response syndrome								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site erythema								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site inflammation								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Vaccination site pruritus								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaccination site reaction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Vessel puncture site bruise								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Xerosis								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye disorders								
All								
Europe	53	(6.9)	74	12.30	54	(7.0)	66	11.30
North America	50	(8.4)	58	12.65	45	(7.8)	62	14.22
South America	10	(7.8)	10	12.75	7	(5.4)	8	10.08
Africa	5	(20.0)	8	53.22	8	(32.0)	12	80.96
Asia	29	(8.2)	38	15.45	38	(9.8)	51	20.13
Diabetic retinopathy								
Europe	14	(1.8)	16	2.91	17	(2.2)	19	3.49
North America	16	(2.7)	16	3.63	17	(3.0)	18	3.92
South America	4	(3.1)	4	5.32	4	(3.1)	4	5.45
Africa	4	(16.0)	5	33.27	5	(20.0)	6	40.48
Asia	14	(3.9)	17	7.76	15	(3.8)	15	5.94
Cataract								
Europe	13	(1.7)	17	2.69	7	(0.9)	8	1.18
North America	5	(0.9)	5	0.89	10	(1.7)	11	2.17
South America	2	(1.5)	2	2.64	0			
Africa	0				2	(8.0)	2	13.49

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	4	(1.1)	5	1.43	6	(1.5)	7	2.79
Retinopathy hypertensive								
Europe	3	(0.4)	4	0.72	5	(0.6)	5	0.96
North America	1	(0.2)	1	0.18	0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Macular oedema								
Europe	3	(0.4)	3	0.59	3	(0.4)	3	0.46
North America	5	(0.8)	5	1.14	1	(0.2)	1	0.16
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Eye pain								
Europe	3	(0.4)	3	0.46	2	(0.3)	2	0.34
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Age-related macular degeneration								
Europe	2	(0.3)	2	0.36	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blepharitis								
Europe	2	(0.3)	2	0.34	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.57	0			
Eye inflammation								
Europe	2	(0.3)	2	0.35	2	(0.2)	2	0.42
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Astigmatism								
Europe	2	(0.3)	3	0.36	1	(0.1)	1	0.21
North America	0				3	(0.5)	3	0.66
South America	0				0			
Africa	0				0			
Asia	0				0			
Presbyopia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.23
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal deposits								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal haemorrhage								
Europe	1	(0.1)	1	0.24	0			
North America	2	(0.3)	2	0.44	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Non-proliferative retinopathy								
Europe	1	(0.1)	2	0.44	1	(0.1)	1	0.23
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Diabetic retinal oedema								
Europe	1	(0.1)	1	0.21	4	(0.5)	5	0.88
North America	1	(0.2)	1	0.27	2	(0.3)	2	0.33
South America	0				0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	1	(0.3)	1	0.47	2	(0.5)	2	0.87
Lacrimation increased								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Myopia								
Europe	1	(0.1)	1	0.21	1	(0.1)	1	0.13
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Amaurosis fugax								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Arteriosclerotic retinopathy								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Conjunctival suffusion								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dry eye								
Europe	1	(0.1)	1	0.12	0			
North America	3	(0.5)	3	0.53	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.81	6	(1.6)	6	1.77
Glaucoma								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.16
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Maculopathy								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitreous opacities								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Conjunctival erosion								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diplopia								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Optic disc vascular disorder								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post thrombotic retinopathy								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal aneurysm								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal tear								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitreous detachment								
Europe	1	(0.1)	1	0.13	0			
North America	2	(0.3)	2	0.44	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acquired epiblepharon								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Angle closure glaucoma								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Asthenopia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Cataract nuclear								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chorioretinal atrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Conjunctival haemorrhage								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Conjunctival hyperaemia								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Conjunctivitis allergic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	3	1.05	0			
Corneal bleeding								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Corneal erosion								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cystoid macular oedema								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Dacryoadenitis acquired								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dry age-related macular degeneration								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Epiretinal membrane								
Europe	0				0			
North America	1	(0.2)	1	0.25	2	(0.3)	2	0.47
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye discharge								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Eye irritation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Eye pruritus								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.2)	2	0.61
South America	0				0			
Africa	0				0			
Asia	0				0			
Eyelid oedema								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypermetropia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Macular degeneration								
Europe	0				1	(0.1)	1	0.13
North America	0				2	(0.4)	2	0.50
South America	0				0			
Africa	0				0			
Asia	0				0			
Macular hole								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Meibomianitis								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Normal tension glaucoma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Ocular hyperaemia								
Europe	0				0			
North America	2	(0.3)	3	0.84	1	(0.2)	2	0.61
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Ocular hypertension								
Europe	0				1	(0.1)	1	0.14
North America	2	(0.3)	2	0.43	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ocular ischaemic syndrome								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Open angle glaucoma								
Europe	0				0			
North America	0				1	(0.2)	2	0.68
South America	0				0			
Africa	0				0			
Asia	0				0			
Ophthalmic vein thrombosis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Optic disc haemorrhage								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Photophobia								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Posterior capsule opacification								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Retinal artery occlusion								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Retinal degeneration								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Retinal detachment								
Europe	0				1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal drusen								
Europe	0				0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal exudates								
Europe	0				0			
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Retinal scar								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal vascular disorder								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Retinal vein occlusion								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.25	0			
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Retinopathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Scintillating scotoma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Uveitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Vision blurred								
Europe	0				1	(0.1)	1	0.14
North America	3	(0.5)	3	0.65	2	(0.4)	2	0.50
South America	1	(0.8)	1	1.32	0			
Africa	0				1	(4.0)	1	6.75
Asia	0				1	(0.3)	1	0.26
Visual acuity reduced								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Visual impairment								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	9	4.19
Vitreous degeneration								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vitreous floaters								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Vitreous haemorrhage								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	2	(0.6)	2	0.99	0			
Metabolism and nutrition disorders								
All								
Europe	50	(6.4)	68	9.98	43	(5.7)	55	8.72
North America	34	(5.9)	43	8.81	34	(5.9)	39	8.46
South America	14	(11.2)	15	16.90	15	(11.4)	16	18.73
Africa	2	(8.0)	2	13.31	2	(8.0)	2	13.49
Asia	24	(6.7)	25	9.57	31	(8.0)	46	15.16
Vitamin D deficiency								
Europe	14	(1.8)	14	1.80	9	(1.2)	9	1.24
North America	2	(0.4)	2	0.35	2	(0.3)	2	0.34
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Hyperlipidaemia								
Europe	7	(0.9)	7	0.94	4	(0.5)	4	0.63
North America	3	(0.5)	3	0.53	7	(1.2)	7	1.33
South America	0				0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	3	(0.8)	3	1.43	1	(0.3)	1	0.47
Vitamin B12 deficiency								
Europe	6	(0.8)	6	0.71	1	(0.1)	1	0.13
North America	5	(0.9)	5	0.88	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoglycaemia								
Europe	5	(0.6)	6	1.05	6	(0.8)	9	1.47
North America	2	(0.3)	6	1.76	3	(0.5)	3	0.81
South America	2	(1.5)	3	4.00	0			
Africa	0				0			
Asia	4	(1.1)	4	1.33	11	(2.8)	24	7.64

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gout								
Europe	4	(0.5)	5	0.61	1	(0.1)	1	0.14
North America	0				5	(0.8)	6	1.01
South America	0				0			
Africa	0				0			
Asia	0				0			
Iron deficiency								
Europe	4	(0.5)	4	0.48	3	(0.4)	3	0.38
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertriglyceridaemia								
Europe	3	(0.4)	3	0.49	2	(0.3)	2	0.34
North America	0				0			
South America	2	(1.6)	2	2.15	3	(2.3)	3	4.03
Africa	0				0			
Asia	5	(1.4)	5	1.61	3	(0.8)	3	0.78
Dyslipidaemia								
Europe	3	(0.4)	3	0.49	6	(0.8)	6	1.03
North America	3	(0.5)	3	0.53	0			
South America	7	(5.6)	7	7.28	8	(6.1)	8	9.24
Africa	0				0			
Asia	8	(2.2)	9	3.69	3	(0.8)	3	1.19
Decreased appetite								
Europe	3	(0.4)	3	0.47	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	4	(0.7)	4	0.83
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperglycaemia								
Europe	3	(0.4)	3	0.55	5	(0.6)	5	0.99
North America	2	(0.3)	3	0.76	3	(0.6)	3	0.84
South America	1	(0.8)	1	1.32	2	(1.5)	2	2.02
Africa	0				0			
Asia	0				4	(1.0)	4	1.25
Hyperuricaemia								
Europe	3	(0.4)	3	0.45	2	(0.3)	2	0.25
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Folate deficiency								
Europe	2	(0.3)	2	0.24	1	(0.1)	1	0.13
North America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Increased appetite								
Europe	2	(0.3)	2	0.25	2	(0.3)	3	0.58
North America	1	(0.2)	1	0.18	3	(0.5)	3	0.77
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Fluid retention								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypercholesterolaemia								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.33
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Hypoalbuminaemia								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypokalaemia								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyponatraemia								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Zinc deficiency								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperkalaemia								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.47
North America	3	(0.5)	4	0.80	4	(0.7)	4	1.02
South America	1	(0.8)	1	0.83	0			
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	2	(0.6)	2	0.76	2	(0.5)	2	0.73
Abnormal weight gain								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Appetite disorder								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	2	0.52
Dehydration								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	1	(0.3)	1	0.26
Diabetes mellitus								
Europe	0				0			
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetes mellitus inadequate control								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrolyte imbalance								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Food craving								
Europe	0				1	(0.1)	1	0.22

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperammonaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Hypercalcaemia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypernatraemia								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Insulin resistance								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Lactic acidosis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipomatosis								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Magnesium deficiency								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Malnutrition								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Metabolic acidosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Metabolic disorder								
Europe	0				0			
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Obesity								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Vitamin B complex deficiency								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Europe	49	(6.3)	78	13.35	44	(5.8)	51	8.21
North America	42	(7.1)	51	10.44	35	(6.1)	42	9.88
South America	4	(3.1)	4	4.83	5	(3.8)	10	9.50
Africa	2	(8.0)	2	13.31	1	(4.0)	1	6.75
Asia	14	(3.9)	16	5.89	16	(4.2)	20	7.06
Oropharyngeal pain								
Europe	8	(1.0)	9	1.25	6	(0.8)	6	0.97
North America	6	(1.0)	6	1.14	6	(1.1)	7	1.94
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				1	(4.0)	1	6.75
Asia	5	(1.4)	6	2.28	3	(0.8)	4	1.25
Cough								
Europe	8	(1.0)	8	1.00	8	(1.1)	8	1.31
North America	9	(1.5)	10	2.22	8	(1.4)	8	1.61
South America	1	(0.8)	1	1.36	0			
Africa	1	(4.0)	1	6.65	0			
Asia	4	(1.1)	4	1.52	4	(1.0)	5	1.71
Rhinorrhoea								
Europe	7	(0.9)	10	1.69	3	(0.4)	3	0.41
North America	3	(0.5)	3	0.68	3	(0.5)	3	0.66
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Respiratory disorder								
Europe	4	(0.5)	4	0.85	4	(0.5)	4	0.69
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Dyspnoea								
Europe	3	(0.4)	3	0.68	6	(0.8)	6	1.02
North America	5	(0.9)	5	1.00	6	(1.1)	7	1.70
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.26
Epistaxis								
Europe	3	(0.4)	7	1.53	1	(0.1)	2	0.42
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.47	1	(0.3)	2	0.52
Sleep apnoea syndrome								
Europe	3	(0.4)	3	0.47	0			
North America	4	(0.7)	4	0.78	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Productive cough								
Europe	3	(0.4)	3	0.55	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Emphysema								
Europe	2	(0.3)	2	0.37	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Pulmonary fibrosis								
Europe	2	(0.3)	3	0.49	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus pain								
Europe	2	(0.3)	3	0.49	0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic obstructive pulmonary disease								
Europe	2	(0.3)	2	0.43	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Nasal congestion								
Europe	2	(0.3)	2	0.34	1	(0.1)	1	0.14
North America	6	(1.0)	6	1.15	3	(0.5)	3	0.50
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.57	0			
Asthma								
Europe	1	(0.1)	1	0.24	0			
North America	3	(0.5)	4	0.80	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Nasal septum deviation								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleurisy								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary hypertension								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acute respiratory failure								
Europe	1	(0.1)	1	0.21	0			
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Nasal obstruction								
Europe	1	(0.1)	1	0.21	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Respiratory failure								
Europe	1	(0.1)	1	0.21	2	(0.3)	2	0.26
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sneezing								
Europe	1	(0.1)	1	0.21	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Rhinitis allergic								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.22
North America	0				2	(0.4)	2	0.64
South America	0				1	(0.7)	5	3.58
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Upper respiratory tract inflammation								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acquired diaphragmatic eventration								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchiectasis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Laryngeal cyst								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nasal dryness								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nasal turbinate hypertrophy								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary embolism								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus congestion								
Europe	1	(0.1)	2	0.25	0			
North America	3	(0.5)	3	0.74	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Throat irritation								
Europe	1	(0.1)	1	0.13	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Acute pulmonary oedema								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Allergic bronchitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Allergic cough								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Aphonia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchitis chronic								
Europe	0				2	(0.3)	2	0.34
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bronchospasm								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Dry throat								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Dysphonia								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	2	2.60
Africa	0				0			
Asia	0				0			
Dyspnoea exertional								
Europe	0				2	(0.3)	2	0.26
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Haemoptysis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Increased viscosity of upper respiratory secretion								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Interstitial lung disease								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	0				0			
Lung disorder								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Paranasal cyst								
Europe	0				1	(0.1)	1	0.21
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Paranasal sinus discomfort								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleural disorder								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleural effusion								
Europe	0				2	(0.3)	2	0.25
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Pleuritic pain								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pulmonary mass								
Europe	0				2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Respiratory tract inflammation								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Upper-airway cough syndrome								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
All								
Europe	44	(5.6)	71	9.40	44	(5.8)	61	8.98
North America	31	(5.3)	40	8.10	19	(3.3)	31	6.54
South America	1	(0.8)	1	1.36	1	(0.8)	1	1.43
Africa	0				1	(4.0)	1	6.75
Asia	10	(2.8)	12	5.22	14	(3.6)	15	5.29
Atrial fibrillation								
Europe	11	(1.4)	12	1.50	4	(0.5)	4	0.61
North America	1	(0.2)	1	0.25	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Cardiac failure								
Europe	8	(1.0)	8	1.08	1	(0.1)	2	0.42
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronary artery disease								
Europe	8	(1.0)	8	1.07	5	(0.6)	5	0.79
North America	4	(0.7)	4	0.80	5	(0.8)	5	0.84
South America	0				0			
Africa	0				0			
Asia	0				0			
Angina pectoris								
Europe	5	(0.6)	5	0.61	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.27	2	(0.4)	2	0.50
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Acute myocardial infarction								
Europe	4	(0.5)	4	0.49	4	(0.5)	4	0.53
North America	4	(0.7)	4	0.92	3	(0.5)	3	0.82
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	1	(0.2)	1	0.41
Acute coronary syndrome								
Europe	3	(0.4)	3	0.37	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Myocardial infarction								
Europe	3	(0.4)	3	0.38	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.25	2	(0.3)	2	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	2	(0.5)	2	0.94	1	(0.3)	1	0.26
Ventricular extrasystoles								
Europe	3	(0.4)	3	0.38	1	(0.1)	2	0.25
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26
Tachycardia								
Europe	2	(0.3)	2	0.24	3	(0.4)	3	0.39
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Cardiac failure chronic								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic valve sclerosis								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrioventricular block first degree								
Europe	1	(0.1)	1	0.22	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mitral valve stenosis								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Supraventricular extrasystoles								
Europe	1	(0.1)	1	0.22	1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Arrhythmia								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.73
Arteriosclerosis coronary artery								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left ventricular hypertrophy								
Europe	1	(0.1)	1	0.12	2	(0.3)	2	0.34
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Angina unstable								
Europe	1	(0.1)	1	0.13	0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Aortic valve incompetence								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial flutter								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial thrombosis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic coronary syndrome								
Europe	1	(0.1)	1	0.13	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronary artery occlusion								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left atrial dilatation								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mitral valve incompetence								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.25
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Myocardial ischaemia								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.26
North America	0				0			
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Palpitations								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.27
North America	4	(0.7)	4	0.83	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	2	(0.5)	2	0.73
Pericardial effusion								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pericarditis								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Sinus tachycardia								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.39
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Tricuspid valve incompetence								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.39
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic valve calcification								
Europe	0				2	(0.3)	2	0.34
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrial enlargement								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Atrioventricular block complete								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Bradycardia								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Bundle branch block left								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Bundle branch block right								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				5	(0.6)	6	0.95
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac arrest								
Europe	0				0			
North America	0				2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac dysfunction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Cardiac failure acute								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac failure congestive								
Europe	0				1	(0.1)	2	0.42
North America	3	(0.5)	3	0.53	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Cardiac flutter								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac perfusion defect								
Europe	0				0			
North America	0				1	(0.2)	2	0.68
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac ventricular thrombosis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Cardio-respiratory arrest								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Coronary artery stenosis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diastolic dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Left atrial enlargement								
Europe	0				0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Left ventricular dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.47
Sinus arrhythmia								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Sinus bradycardia								
Europe	0				2	(0.3)	2	0.26
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Subendocardial ischaemia								
Europe	0				2	(0.3)	2	0.25
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Supraventricular tachycardia								
Europe	0				0			
North America	2	(0.3)	2	0.43	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ventricular arrhythmia								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ventricular tachycardia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin and subcutaneous tissue disorders								
All								
Europe	36	(4.6)	38	5.59	30	(4.0)	36	5.36
North America	30	(5.1)	34	7.09	39	(6.7)	47	9.92
South America	1	(0.8)	1	1.32	5	(3.9)	5	6.76
Africa	1	(4.0)	1	6.65	0			
Asia	31	(8.8)	33	12.95	30	(7.8)	35	12.03
Pruritus								
Europe	5	(0.6)	5	0.70	3	(0.4)	3	0.40
North America	2	(0.3)	2	0.44	5	(0.9)	5	1.15
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	1	(0.3)	1	0.48	2	(0.5)	2	0.93
Urticaria								
Europe	4	(0.5)	4	0.57	4	(0.5)	4	0.52
North America	1	(0.2)	1	0.25	3	(0.5)	3	0.50
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.6)	2	0.99	1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eczema								
Europe	4	(0.5)	4	0.50	2	(0.3)	2	0.33
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	5	(1.4)	5	2.04	4	(1.0)	4	1.60
Rash								
Europe	3	(0.4)	3	0.56	3	(0.4)	3	0.41
North America	5	(0.9)	5	0.98	6	(1.0)	7	1.35
South America	0				0			
Africa	0				0			
Asia	3	(0.9)	3	1.33	2	(0.5)	2	0.67
Skin ulcer								
Europe	2	(0.3)	2	0.37	1	(0.1)	1	0.13
North America	2	(0.3)	2	0.44	2	(0.4)	2	0.64
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Hyperkeratosis								
Europe	2	(0.3)	2	0.35	0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Ingrowing nail								
Europe	2	(0.3)	2	0.25	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.52
Dermatitis contact								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.27
North America	1	(0.2)	1	0.18	3	(0.5)	3	0.53
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	2	(0.6)	3	0.86	2	(0.5)	2	0.73
Umbilical haematoma								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Decubitus ulcer								
Europe	1	(0.1)	1	0.22	1	(0.1)	1	0.13
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperhidrosis								
Europe	1	(0.1)	1	0.21	3	(0.4)	3	0.57
North America	2	(0.4)	2	0.35	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	5	(1.4)	5	1.99	0			
Erythema								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	0				2	(0.3)	2	0.47
South America	0				0			
Africa	0				0			
Asia	0				0			
Livedo reticularis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nail bed inflammation								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Night sweats								
Europe	1	(0.1)	1	0.12	0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Dermatitis								
Europe	1	(0.1)	1	0.13	4	(0.5)	4	0.63
North America	2	(0.3)	2	0.47	2	(0.3)	3	0.78
South America	0				0			
Africa	0				0			
Asia	0				0			
Dermatitis allergic								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dry skin								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				3	(0.5)	3	0.63
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.57	0			
Granuloma annulare								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipodystrophy acquired								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Psoriasis								
Europe	1	(0.1)	1	0.13	0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Skin exfoliation								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Acne								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Actinic keratosis								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Alopecia								
Europe	0				1	(0.1)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	5	(0.8)	5	1.05	2	(0.3)	2	0.35
South America	0				0			
Africa	0				0			
Asia	0				0			
Alopecia areata								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Angioedema								
Europe	0				2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Asteatosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Blister								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				1	(0.3)	1	0.26
Cold sweat								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	4	(1.1)	4	1.51	3	(0.8)	3	0.99
Cold urticaria								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Dermal cyst								
Europe	0				1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.3)	1	0.26
Diabetic foot								
Europe	0				2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug eruption								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Ecchymosis								
Europe	0				0			
North America	1	(0.2)	1	0.29	2	(0.3)	2	0.35
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemorrhage subcutaneous								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Hidradenitis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Intertrigo								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lentigo								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Leukoplakia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Lipohypertrophy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.73
Macule								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Miliaria								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	1.05	3	(0.8)	3	0.78
Myxoid cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Neurodermatitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Pruritus allergic								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Purpura								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Rash erythematous								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Rash maculo-papular								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Rash papular								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Seborrhoea								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin discolouration								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Skin fissures								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Skin irritation								
Europe	0				0			
North America	2	(0.4)	3	0.53	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Skin lesion								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin odour abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin reaction								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Urticaria contact								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Urticaria thermal								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vascular disorders								
All								
Europe	35	(4.5)	41	6.77	43	(5.6)	54	8.72
North America	20	(3.5)	22	4.22	13	(2.3)	17	3.31
South America	5	(3.9)	5	6.11	4	(3.1)	4	5.33
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	12	(3.3)	13	4.65	15	(3.9)	19	7.36
Hypertension								
Europe	13	(1.6)	13	2.06	12	(1.6)	14	2.15
North America	8	(1.4)	8	1.65	8	(1.4)	9	2.00
South America	3	(2.4)	3	3.47	3	(2.3)	3	3.91
Africa	1	(4.0)	1	6.65	1	(4.0)	1	6.75
Asia	7	(1.9)	7	2.56	11	(2.8)	13	4.77

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral arterial occlusive disease								
Europe	3	(0.4)	3	0.58	2	(0.3)	2	0.27
North America	1	(0.2)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypotension								
Europe	3	(0.4)	3	0.47	2	(0.3)	2	0.34
North America	2	(0.4)	2	0.35	1	(0.2)	1	0.16
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Peripheral artery stenosis								
Europe	2	(0.3)	5	0.98	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arteriosclerosis								
Europe	2	(0.3)	2	0.25	5	(0.7)	5	0.73
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Superficial vein thrombosis								
Europe	2	(0.3)	2	0.25	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic arteriosclerosis								
Europe	2	(0.3)	2	0.25	4	(0.5)	4	0.77
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Diabetic vascular disorder								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Haematoma								
Europe	1	(0.1)	1	0.24	3	(0.4)	3	0.56
North America	1	(0.2)	1	0.18	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertensive crisis								
Europe	1	(0.1)	1	0.24	2	(0.3)	4	0.76
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral venous disease								
Europe	1	(0.1)	1	0.24	2	(0.3)	2	0.26
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Orthostatic hypotension								
Europe	1	(0.1)	1	0.21	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Venous stenosis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Brachiocephalic arteriosclerosis								
Europe	1	(0.1)	1	0.13	3	(0.4)	3	0.41
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Flushing								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral artery occlusion								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral coldness								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.57	1	(0.3)	1	0.26
Peripheral vascular disorder								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aneurysm								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic aneurysm								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Aortic dilatation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Aortic stenosis								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Arterial insufficiency								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Blood pressure fluctuation								
Europe	0				1	(0.1)	1	0.21

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood pressure inadequately controlled								
Europe	0				2	(0.3)	2	0.26
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Deep vein thrombosis								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hot flush								
Europe	0				1	(0.1)	1	0.22
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypertensive urgency								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	2	0.33
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Iliac artery stenosis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Intermittent claudication								
Europe	0				2	(0.3)	2	0.26
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Macroangiopathy								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Neovascularisation								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral artery aneurysm								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Peripheral ischaemia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Phlebitis								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombophlebitis								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombosis								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Varicose ulceration								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Investigations								
All								
Europe	29	(3.7)	35	5.61	22	(2.9)	23	3.45
North America	39	(6.6)	45	9.88	29	(5.1)	30	6.99
South America	1	(0.8)	1	1.32	3	(2.3)	3	3.57
Africa	0				0			
Asia	11	(3.1)	13	4.89	12	(3.1)	17	6.78
SARS-CoV-2 test positive								
Europe	5	(0.7)	5	0.93	0			
North America	2	(0.3)	2	0.55	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood creatinine increased								
Europe	5	(0.7)	5	1.01	0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	1.00	0			
Blood pressure increased								
Europe	3	(0.4)	3	0.47	2	(0.3)	2	0.34
North America	0				2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood immunoglobulin E increased								
Europe	3	(0.4)	3	0.36	3	(0.4)	3	0.38
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Weight increased								
Europe	3	(0.4)	3	0.36	4	(0.5)	4	0.63
North America	14	(2.3)	14	3.25	9	(1.6)	9	2.15
South America	0				3	(2.3)	3	3.57
Africa	0				0			
Asia	2	(0.6)	2	0.57	2	(0.5)	2	0.52
Blood triglycerides increased								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	2	(0.3)	2	0.36	0			
North America	1	(0.2)	1	0.18	2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Occult blood								
Europe	2	(0.3)	2	0.34	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophil count increased								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Arthroscopy								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Alanine aminotransferase increased								
Europe	1	(0.1)	1	0.21	0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	2	(0.6)	2	0.76	0			
Electrocardiogram T wave inversion								
Europe	1	(0.1)	1	0.12	0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
QRS axis abnormal								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Blood creatine increased								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Body temperature increased								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio abnormal								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio decreased								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
International normalised ratio increased								
Europe	1	(0.1)	2	0.25	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Weight decreased								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Amylase increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Antinuclear antibody positive								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Aspartate aminotransferase increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.26
Blood alkaline phosphatase increased								
Europe	0				0			
North America	3	(0.5)	3	0.86	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood cholesterol increased								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood creatine phosphokinase increased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Blood glucose decreased								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood glucose fluctuation								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Blood glucose increased								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood potassium increased								
Europe	0				1	(0.1)	1	0.23
North America	1	(0.2)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood pressure decreased								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood urine present								
Europe	0				0			
North America	1	(0.2)	3	0.53	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Bone density decreased								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Breath sounds abnormal								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Carbohydrate antigen 19-9 increased								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac murmur								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac stress test abnormal								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Catheterisation cardiac								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ejection fraction decreased								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.18	2	(0.4)	2	0.50
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram P wave biphasic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Electrocardiogram repolarisation abnormality								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram ST segment abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Electrocardiogram ST segment depression								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Free fatty acids increased								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Glomerular filtration rate decreased								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Glycosylated haemoglobin increased								
Europe	0				2	(0.3)	3	0.38
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Grip strength decreased								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematocrit increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Haemoglobin decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Haemoglobin increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Hepatic enzyme increased								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Intraocular pressure increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipase increased								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipids increased								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Liver function test abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	2	0.82
Liver function test increased								
Europe	0				0			
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Low density lipoprotein increased								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Monocyte count decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	1	(0.3)	1	0.47
Monofilament pressure perception test								

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Platelet count decreased								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				2	(0.5)	2	0.93
Prostatic specific antigen increased								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Red blood cell count decreased								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Thyroid function test abnormal								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Transaminases increased								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Transferrin saturation decreased								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vitamin D decreased								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Renal and urinary disorders								
All								
Europe	23	(2.9)	32	5.12	18	(2.4)	25	3.77
North America	16	(2.8)	18	4.00	16	(2.7)	21	3.78
South America	1	(0.8)	1	1.32	5	(3.8)	5	5.46
Africa	2	(8.0)	2	13.31	0			
Asia	9	(2.5)	9	3.80	12	(3.1)	13	4.62
Nephrolithiasis								
Europe	4	(0.5)	4	0.48	1	(0.1)	2	0.44
North America	1	(0.2)	1	0.18	2	(0.3)	3	0.50
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Chronic kidney disease								
Europe	3	(0.4)	3	0.61	2	(0.3)	2	0.26
North America	0				1	(0.2)	1	0.16
South America	1	(0.8)	1	1.32	1	(0.8)	1	1.43
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Dysuria								
Europe	3	(0.4)	4	0.60	2	(0.3)	2	0.27
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	2	(0.5)	2	0.73
Ureterolithiasis								
Europe	3	(0.4)	3	0.47	0			
North America	0				2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Diabetic nephropathy								
Europe	3	(0.4)	3	0.47	0			
North America	0				0			
South America	0				2	(1.5)	2	2.60
Africa	0				0			
Asia	0				0			
Urine odour abnormal								
Europe	2	(0.3)	2	0.34	0			
North America	0				1	(0.2)	1	0.30
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Renal cyst								
Europe	2	(0.3)	2	0.25	3	(0.4)	3	0.46
North America	2	(0.3)	2	0.43	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	3	(0.8)	3	1.42	0			
Acute kidney injury								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.13
North America	2	(0.3)	2	0.47	4	(0.7)	4	0.67
South America	0				0			
Africa	0				0			
Asia	0				0			
Haematuria								
Europe	1	(0.1)	2	0.48	3	(0.4)	3	0.49
North America	0				2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal failure								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Polyuria								
Europe	1	(0.1)	1	0.21	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal pain								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Calculus urinary								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Microalbuminuria								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pollakiuria								
Europe	1	(0.1)	1	0.13	0			
North America	3	(0.5)	3	0.88	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	2	(0.5)	2	0.52
Pyelocaliectasis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal colic								
Europe	1	(0.1)	1	0.13	2	(0.3)	2	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Bladder mass								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Bladder prolapse								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Chromaturia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Cystitis haemorrhagic								
Europe	0				0			
North America	0				1	(0.2)	1	0.16

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydrocalyx								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydronephrosis								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Hypertonic bladder								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Micturition urgency								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
Nephropathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Nephrotic syndrome								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Nocturia								
Europe	0				1	(0.1)	1	0.14
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Proteinuria								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal impairment								
Europe	0				1	(0.1)	1	0.14
North America	2	(0.3)	2	0.47	1	(0.2)	1	0.16
South America	0				1	(0.7)	1	0.72
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.29	0			
Renal mass								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Strangury								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Stress urinary incontinence								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urethral stenosis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	0				0			
Urinary incontinence								
Europe	0				1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			
Urinary retention								
Europe	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract disorder								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract inflammation								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Urinary tract obstruction								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Europe	15	(1.9)	20	3.14	11	(1.5)	18	2.79
North America	7	(1.2)	10	1.89	11	(1.9)	15	2.86
South America	1	(0.8)	1	1.32	0			
Africa	1	(4.0)	1	6.65	0			
Asia	7	(2.0)	7	2.85	5	(1.2)	7	2.47
Pancreatic neoplasm								
Europe	2	(0.3)	2	0.37	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to liver								
Europe	2	(0.3)	2	0.25	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Seborrhoeic keratosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	2	(0.3)	3	0.38	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eye naevus								
Europe	1	(0.1)	1	0.24	0			
North America	1	(0.2)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Osteoma								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Small cell lung cancer								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bladder papilloma								
Europe	1	(0.1)	1	0.22	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lung cancer metastatic								
Europe	1	(0.1)	1	0.22	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Colon adenoma								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	1	(4.0)	1	6.65	0			
Asia	1	(0.3)	1	0.48	0			
Colorectal cancer								
Europe	1	(0.1)	1	0.12	0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Pancreatic carcinoma								
Europe	1	(0.1)	1	0.12	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal neoplasm								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Basal cell carcinoma								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	0				2	(0.3)	2	0.35
South America	0				0			
Africa	0				0			
Asia	0				0			
Glioblastoma multiforme								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Oral fibroma								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Salivary gland neoplasm								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Acrochordon								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Adenocarcinoma of colon								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Adenocarcinoma pancreas								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Adrenal adenoma								
Europe	0				2	(0.3)	2	0.43
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Benign renal neoplasm								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Bladder cancer								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bowen's disease								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Breast cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Breast cancer metastatic								
Europe	0				1	(0.1)	1	0.13
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Chronic myeloid leukaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Colon cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Colon cancer stage II								
Europe	0				0			
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysplastic naevus								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Endometrial adenocarcinoma								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Gastric cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Gastrointestinal tract adenoma								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemangioma of liver								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Hepatocellular carcinoma								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Invasive breast carcinoma								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Invasive ductal breast carcinoma								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Invasive lobular breast carcinoma								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lipoma								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Lung adenocarcinoma								
Europe	0				1	(0.1)	1	0.22
North America	0				1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Lymphangioma								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Malignant melanoma								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malignant melanoma in situ								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Malignant peritoneal neoplasm								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to bone marrow								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Metastases to lymph nodes								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Myxoma								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Neoplasm skin								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	1	(0.3)	1	0.29	0			
Ovarian cancer metastatic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Pancreatic carcinoma metastatic								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Prostate cancer								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Prostatic adenoma								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal cell carcinoma								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Renal hamartoma								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin papilloma								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Small intestine neuroendocrine tumour								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Squamous cell carcinoma of skin								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine cancer								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine leiomyoma								
Europe	0				2	(0.3)	2	0.33
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Blood and lymphatic system disorders								
All								
Europe	12	(1.5)	12	1.82	9	(1.2)	9	1.27
North America	9	(1.6)	9	1.80	8	(1.4)	8	1.65
South America	4	(3.1)	4	4.79	6	(4.4)	6	5.59
Africa	1	(4.0)	3	19.96	0			
Asia	7	(1.9)	7	2.93	7	(1.8)	7	2.85
Anaemia								
Europe	7	(0.9)	7	1.09	3	(0.4)	3	0.39
North America	5	(0.9)	5	1.00	4	(0.7)	4	0.98
South America	3	(2.3)	3	3.96	5	(3.7)	5	4.88
Africa	1	(4.0)	3	19.96	0			
Asia	3	(0.8)	3	1.23	2	(0.5)	2	0.73
Lymphadenopathy mediastinal								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Leukocytosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	1	(0.1)	1	0.12	3	(0.4)	3	0.38
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Splenomegaly								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Iron deficiency anaemia								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.14
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	1	(0.3)	1	0.47
Polycythaemia								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Blood loss anaemia								
Europe	0				0			
North America	1	(0.2)	1	0.27	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Eosinophilia								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	0.83	1	(0.7)	1	0.72
Africa	0				0			
Asia	1	(0.3)	1	0.47	1	(0.3)	1	0.47
Hypochromic anaemia								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Leukopenia								
Europe	0				0			
North America	0				0			
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Lymphadenopathy								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Normocytic anaemia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Pancytopenia								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Thrombocytopenia								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Thrombocytosis								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Psychiatric disorders								
All								
Europe	9	(1.1)	10	1.32	18	(2.4)	19	3.36
North America	16	(2.7)	19	3.77	14	(2.5)	15	3.31
South America	4	(3.1)	4	4.79	1	(0.8)	1	1.43
Africa	0				1	(4.0)	1	6.75
Asia	7	(2.0)	7	2.62	3	(0.8)	3	1.19
Sleep disorder								
Europe	3	(0.4)	3	0.36	1	(0.1)	1	0.23
North America	1	(0.2)	1	0.18	2	(0.4)	2	0.67
South America	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Insomnia								
Europe	2	(0.3)	2	0.34	2	(0.3)	3	0.58
North America	1	(0.2)	1	0.25	2	(0.3)	2	0.34
South America	2	(1.6)	2	2.15	0			
Africa	0				0			
Asia	5	(1.4)	5	1.67	2	(0.5)	2	0.73
Anxiety								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.27
North America	2	(0.4)	2	0.35	4	(0.7)	4	0.66
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Depression								
Europe	1	(0.1)	1	0.12	3	(0.4)	3	0.49
North America	7	(1.2)	7	1.41	5	(0.9)	5	1.17
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Listless								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Depressed mood								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adjustment disorder								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adjustment disorder with depressed mood								
Europe	0				0			
North America	0				1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Adjustment disorder with mixed anxiety and depressed mood								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Affect lability								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Agitation								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Anxiety disorder								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Bruxism								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Disorientation								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug abuse								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Drug dependence								
Europe	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Emotional distress								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Fear								
Europe	0				2	(0.2)	2	0.42
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Irritability								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Major depression								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Mental status changes								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mixed anxiety and depressive disorder								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Mood swings								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			

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Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Nightmare								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Persistent depressive disorder								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Phobia								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Post-traumatic stress disorder								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Stress								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear and labyrinth disorders								
All								
Europe	8	(1.0)	8	1.08	12	(1.6)	12	2.11
North America	13	(2.2)	16	3.07	6	(1.1)	7	1.66
South America	1	(0.8)	1	1.32	1	(0.7)	1	0.72
Africa	0				0			
Asia	4	(1.1)	4	1.76	3	(0.8)	3	0.99
Vertigo								
Europe	3	(0.4)	3	0.47	2	(0.3)	2	0.34
North America	4	(0.7)	5	0.96	3	(0.5)	4	0.85
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	3	(0.8)	3	1.24	3	(0.8)	3	0.99
Tinnitus								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.37
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypoacusis								
Europe	1	(0.1)	1	0.12	3	(0.4)	3	0.39
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Ear inflammation								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear pain								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.23
North America	3	(0.5)	3	0.61	0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Cerumen impaction								
Europe	0				0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.34
South America	0				0			
Africa	0				0			
Asia	0				0			
Deafness bilateral								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Deafness unilateral								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Ear 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Eustachian tube dysfunction								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.30
South America	0				0			
Africa	0				0			
Asia	0				0			
External ear pain								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Meniere's disease								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Middle ear inflammation								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Motion sickness								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Presbyacusis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vertigo positional								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				1	(0.7)	1	0.72

%: Percentage of subjects with one or more events, E: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Hepatobiliary disorders								
All								
Europe	7	(0.9)	10	1.45	13	(1.7)	13	2.10
North America	1	(0.2)	2	0.35	1	(0.2)	2	0.33
South America	2	(1.7)	3	2.49	1	(0.7)	1	0.72
Africa	0				0			
Asia	9	(2.6)	10	4.08	6	(1.6)	9	3.37
Hepatic steatosis								
Europe	3	(0.4)	3	0.37	4	(0.5)	4	0.50
North America	1	(0.2)	1	0.18	0			
South America	1	(0.8)	1	0.83	0			
Africa	0				0			
Asia	3	(0.8)	3	1.05	5	(1.3)	5	1.92
Hepatomegaly								
Europe	2	(0.3)	2	0.36	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholelithiasis								
Europe	2	(0.3)	2	0.24	1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Cholecystitis chronic								
Europe	1	(0.1)	1	0.24	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hepatic mass								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Gallbladder cholesterolosis								
Europe	1	(0.1)	1	0.13	0			
North America	0				0			
South America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Alcoholic liver disease								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Bile duct stone								
Europe	0				0			
North America	0				1	(0.2)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Biliary colic								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Biliary dyskinesia								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cholecystitis								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Gallbladder polyp								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	1	(0.3)	1	0.47
Hepatic cirrhosis								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				1	(0.7)	1	0.72
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatic cyst								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Hepatic function abnormal								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	2	(0.5)	2	0.73
Hyperplastic cholecystopathy								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.47	0			
Hypertransaminasaemia								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	2	1.66	0			
Africa	0				0			
Asia	0				0			
Liver disorder								
Europe	0				1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Non-alcoholic steatohepatitis								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Nonalcoholic fatty liver disease								
Europe	0				2	(0.3)	2	0.26
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Steatohepatitis								
Europe	0				1	(0.1)	1	0.14
North America	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Reproductive system and breast disorders								
All								
Europe	7	(0.9)	7	0.86	6	(0.8)	8	1.16
North America	10	(1.7)	10	1.92	10	(1.7)	12	2.16
South America	5	(3.9)	5	6.64	2	(1.5)	2	2.60
Africa	0				1	(4.0)	1	6.75
Asia	7	(2.0)	7	2.66	4	(1.0)	4	1.25
Atrophic vulvovaginitis								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Benign prostatic hyperplasia								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	2	(0.4)	2	0.51
South America	1	(0.8)	1	1.36	0			
Africa	0				0			
Asia	2	(0.6)	2	0.81	0			
Menstruation irregular								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Breast mass								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Erectile dysfunction								
Europe	1	(0.1)	1	0.13	0			
North America	3	(0.5)	3	0.61	0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Uterine prolapse								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
South America	0				0			
Africa	0				0			
Asia	0				0			
Vulvovaginal pruritus								
Europe	1	(0.1)	1	0.13	0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Breast pain								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Cervical polyp								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.52	0			
Colpocele								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Dysmenorrhoea								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Ejaculation failure								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Galactorrhoea								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Genital prolapse								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Intermenstrual bleeding								
Europe	0				0			
North America	0				0			
South America	2	(1.5)	2	2.64	0			
Africa	0				0			
Asia	0				0			
Menopausal disorder								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Menopausal symptoms								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Menstruation delayed								
Europe	0				0			
North America	0				0			
South America	1	(0.8)	1	1.32	0			
Africa	0				0			
Asia	0				0			
Ovarian cyst								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Pelvic discomfort								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Penile rash								
Europe	0				1	(0.1)	2	0.27

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Prostatic calcification								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.48	0			
Prostatitis								
Europe	0				0			
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Pruritus genital								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	1	(0.3)	1	0.26
Testicular cyst								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine enlargement								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Uterine polyp								
Europe	0				0			
North America	2	(0.4)	2	0.35	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Vaginal discharge								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				1	(0.8)	1	1.30
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Vaginal haemorrhage								
Europe	0				0			
North America	0				2	(0.3)	2	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Vulvovaginal dryness								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Immune system disorders								
All								
Europe	3	(0.4)	4	0.61	5	(0.7)	6	1.09
North America	9	(1.5)	9	1.93	8	(1.4)	8	2.03
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Seasonal allergy								
Europe	2	(0.3)	2	0.25	2	(0.3)	2	0.37
North America	6	(1.0)	6	1.23	6	(1.1)	6	1.53
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypersensitivity								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Allergy to arthropod bite								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.22
North America	0				1	(0.2)	1	0.33
South America	0				0			
Africa	0				0			
Asia	0				0			
Allergy to arthropod sting								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				1	(0.2)	1	0.41
Anaphylactic reaction								
Europe	0				1	(0.1)	1	0.23
North America	1	(0.2)	1	0.25	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Drug hypersensitivity								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Food allergy								
Europe	0				0			
North America	1	(0.2)	1	0.18	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Immunisation reaction								
Europe	0				1	(0.1)	2	0.27
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Surgical and medical procedures								
All								
Europe	2	(0.3)	2	0.36	3	(0.4)	3	0.56
North America	2	(0.3)	2	0.44	2	(0.3)	2	0.34
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Tooth extraction								
Europe	1	(0.1)	1	0.24	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cardiac pacemaker replacement								
Europe	1	(0.1)	1	0.12	1	(0.1)	1	0.21
North America	0				0			
South America	0				0			
Africa	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asia	0				0			
Knee operation								
Europe	0				0			
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Large intestinal polypectomy								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Removal of foreign body								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Shoulder operation								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Skin neoplasm excision								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Spinal operation								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Toe amputation								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Endocrine disorders								
All								
Europe	2	(0.3)	2	0.25	9	(1.2)	9	1.28
North America	4	(0.7)	4	0.89	2	(0.3)	2	0.33
South America	0				2	(1.5)	2	2.73
Africa	0				1	(4.0)	1	6.75
Asia	0				4	(1.0)	4	1.40
Autoimmune thyroiditis								
Europe	1	(0.1)	1	0.12	0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Thyroid mass								
Europe	1	(0.1)	1	0.13	1	(0.1)	1	0.13
North America	1	(0.2)	1	0.18	0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.47
Adrenal mass								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Adrenocortical insufficiency acute								
Europe	0				1	(0.1)	1	0.23
North America	0				0			
South America	0				1	(0.8)	1	1.43
Africa	0				0			
Asia	0				0			
Goitre								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Hyperplasia adrenal								
Europe	0				1	(0.1)	1	0.14
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hyperprolactinaemia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				1	(0.3)	1	0.26
Hyperthyroidism								
Europe	0				2	(0.3)	2	0.26
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypogonadism								
Europe	0				0			
North America	1	(0.2)	1	0.27	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Hypothyroidism								
Europe	0				2	(0.3)	2	0.26
North America	2	(0.3)	2	0.44	1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				1	(0.2)	1	0.41
Inappropriate antidiuretic hormone secretion								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				1	(4.0)	1	6.75
Asia	0				0			
Secondary hypogonadism								
Europe	0				0			
North America	0				0			
South America	0				1	(0.8)	1	1.30
Africa	0				0			
Asia	0				0			
Congenital, familial and genetic disorders								
All								
Europe	0				2	(0.3)	2	0.25
North America	2	(0.3)	2	0.56	2	(0.3)	2	0.34
South America	3	(2.4)	3	3.47	1	(0.8)	1	1.30
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Atrial septal defect								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Congenital syphilitic osteochondritis								
Europe	0				0			
North America	0				1	(0.2)	1	0.18
South America	0				0			
Africa	0				0			
Asia	0				0			
Corneal dystrophy								
Europe	0				0			
North America	1	(0.2)	1	0.27	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Cystic fibrosis lung								
Europe	0				0			
North America	1	(0.2)	1	0.29	0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Hydrocele								
Europe	0				0			
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	1	(0.3)	1	0.29	0			
Hypertrophic cardiomyopathy								
Europe	0				1	(0.1)	1	0.13
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Myotonic dystrophy								
Europe	0				0			
North America	0				1	(0.2)	1	0.16
South America	0				0			
Africa	0				0			
Asia	0				0			
Type V hyperlipidaemia								
Europe	0				0			
North America	0				0			
South America	3	(2.4)	3	3.47	1	(0.8)	1	1.30

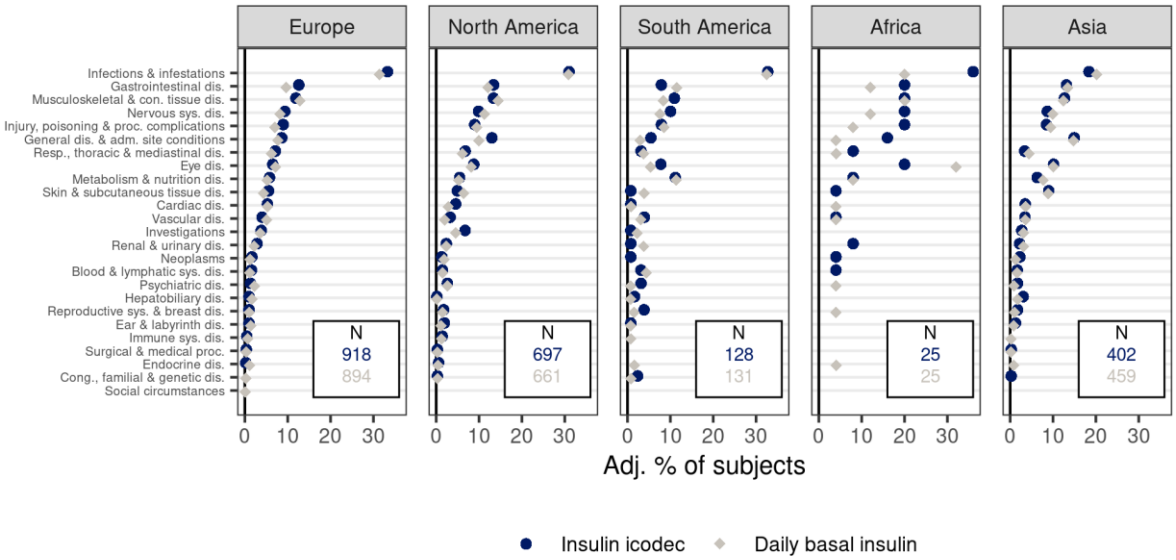
%: Percentage of subjects with one or more events, E: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by region, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Africa	0				0			
Asia	0				0			
Social circumstances								
All								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			
Menopause								
Europe	0				1	(0.1)	1	0.22
North America	0				0			
South America	0				0			
Africa	0				0			
Asia	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.7.37 Adverse events by region and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

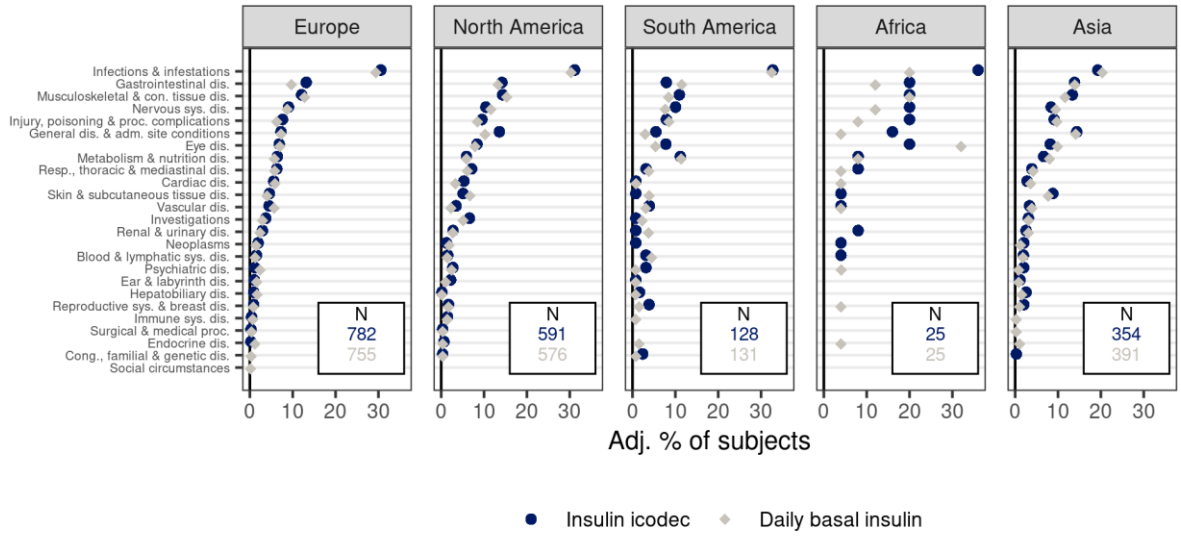


% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): REGION1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS REGION1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
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7.7.38 Adverse events by region and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool

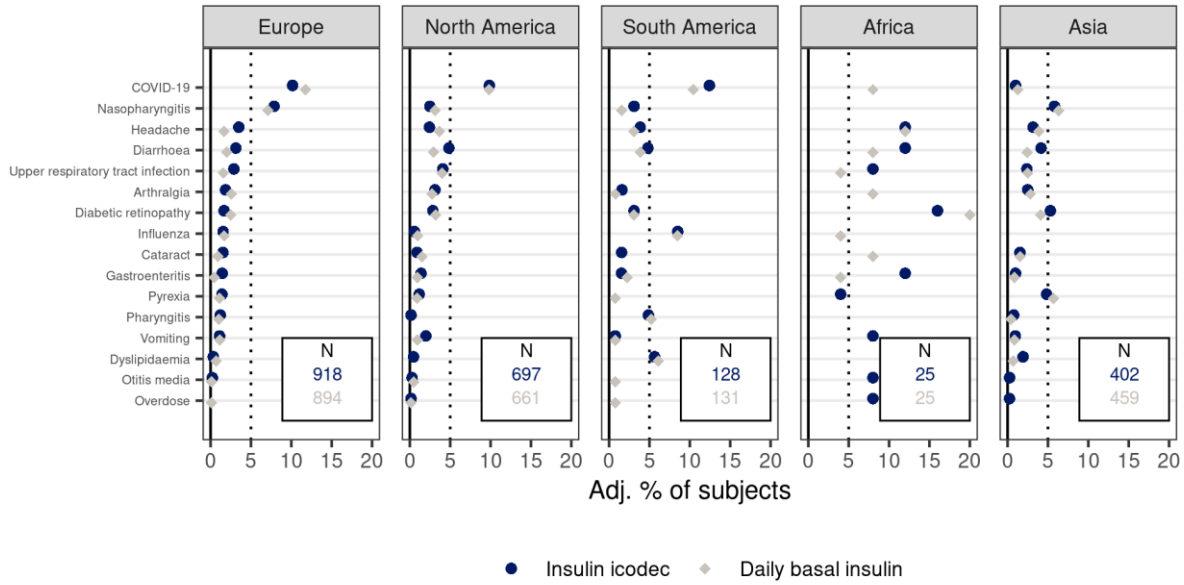


% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): REGION1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS REGION1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
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7.7.39 Adverse events by region and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

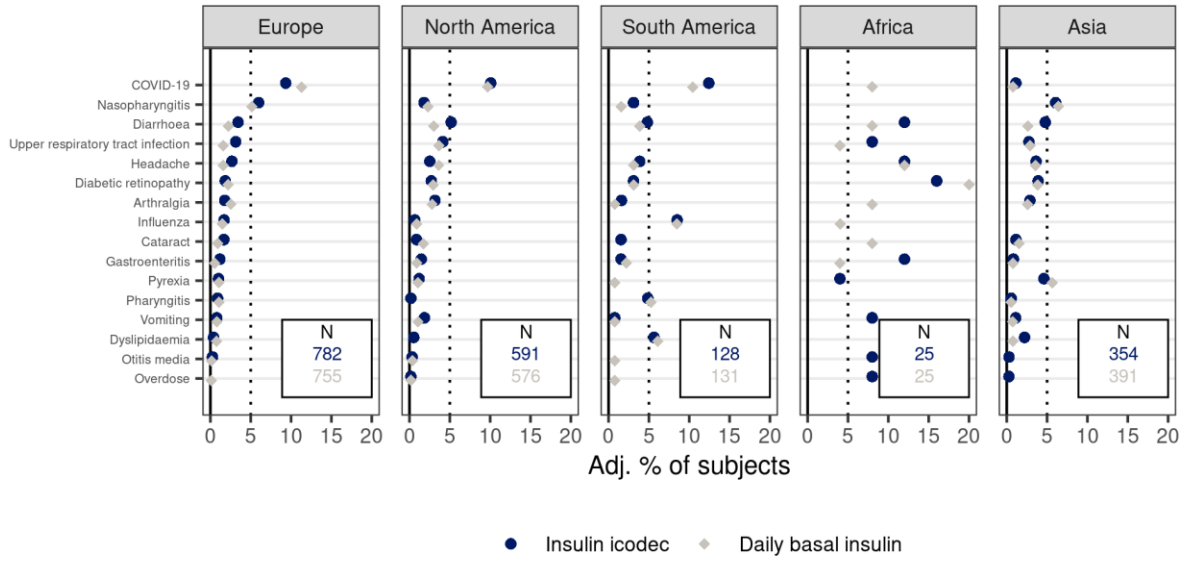


% of subjects: Percentage of subjects with one or more events, N: Number of subjects. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): REGION1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD REGION1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:45 - faedotgrp/faept5pctgrpregiondotontp3asas.png

7.7.40 Adverse events by region and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. For South America, only ONWARDS 1, 3 and 4 contribute. For Africa, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For Asia, all trials except ONWARDS 5 contribute. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): REGION1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD REGION1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:50 - faedotgrp/faept5pctgrpregiondotontt2dsas.png

7.7.41 Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
<8% (<64 mmol/mol)	888				897			
>=8% (>=64 mmol/mol)	1282				1272			
Missing	0				1			
PYE (years)								
<8% (<64 mmol/mol)	649.98				659.50			
>=8% (>=64 mmol/mol)	1031.26				1020.75			
Missing	0.00				0.33			
Events								
<8% (<64 mmol/mol)	540	(61.0)	1606	265.58	528	(58.7)	1647	269.76
>=8% (>=64 mmol/mol)	788	(61.4)	2379	247.36	735	(57.9)	2231	237.29
Missing	0				0			
Serious								
Yes								
<8% (<64 mmol/mol)	61	(6.9)	82	12.35	58	(6.4)	79	11.00
>=8% (>=64 mmol/mol)	105	(8.2)	163	16.55	111	(8.7)	159	15.56
Missing	0				0			
No								
<8% (<64 mmol/mol)	528	(59.6)	1524	253.23	515	(57.3)	1568	258.76
>=8% (>=64 mmol/mol)	759	(59.2)	2216	230.81	708	(55.7)	2072	221.73
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Severity								
Severe								
<8% (<64 mmol/mol)	31	(3.5)	37	5.91	27	(3.0)	37	5.30
>=8% (>=64 mmol/mol)	61	(4.8)	84	8.96	62	(4.9)	96	8.74
Missing	0				0			
Moderate								
<8% (<64 mmol/mol)	193	(21.8)	357	57.44	181	(20.1)	349	54.31
>=8% (>=64 mmol/mol)	319	(24.8)	574	56.98	297	(23.4)	507	51.22
Missing	0				0			
Mild								
<8% (<64 mmol/mol)	459	(51.9)	1212	202.23	459	(51.0)	1261	210.14
>=8% (>=64 mmol/mol)	654	(51.0)	1721	181.42	614	(48.3)	1628	177.33
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	29	(3.3)	43	6.99	32	(3.6)	46	7.50
>=8% (>=64 mmol/mol)	53	(4.1)	77	9.19	44	(3.5)	87	8.45
Missing	0				0			
Possible								
<8% (<64 mmol/mol)	58	(6.6)	84	14.62	46	(5.1)	98	17.49
>=8% (>=64 mmol/mol)	67	(5.2)	95	10.87	59	(4.6)	80	8.92
Missing	0				0			
Unlikely								
<8% (<64 mmol/mol)	523	(59.0)	1473	242.91	515	(57.3)	1499	244.25
>=8% (>=64 mmol/mol)	753	(58.7)	2201	226.55	711	(56.0)	2062	219.65
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	4	(0.5)	6	1.06	4	(0.4)	4	0.52
>=8% (>=64 mmol/mol)	4	(0.3)	6	0.75	2	(0.2)	2	0.27
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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	5	(0.6)	5	0.97	3	(0.3)	4	0.78
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.81	4	(0.3)	4	0.54
Missing	0				0			
No								
<8% (<64 mmol/mol)	538	(60.7)	1595	263.56	524	(58.3)	1638	268.27
>=8% (>=64 mmol/mol)	787	(61.3)	2366	245.66	734	(57.8)	2224	236.34
Missing	0				0			
NA								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	4	(0.5)	6	1.06	4	(0.4)	4	0.52
>=8% (>=64 mmol/mol)	4	(0.3)	6	0.75	3	(0.2)	3	0.41
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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Outcome								
Fatal								
<8% (<64 mmol/mol)	4	(0.5)	5	0.83	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	10	(0.8)	13	1.41	12	(0.9)	14	1.31
Missing	0				0			
Not recovered/not resolved								
<8% (<64 mmol/mol)	235	(26.5)	411	66.28	223	(24.8)	422	68.89
>=8% (>=64 mmol/mol)	354	(27.6)	676	68.77	347	(27.3)	620	62.69
Missing	0				0			
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	5	(0.6)	5	0.67	7	(0.8)	8	1.28
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	9	(0.7)	10	0.98
Missing	0				0			
Recovering/resolving								
<8% (<64 mmol/mol)	37	(4.2)	51	8.13	32	(3.6)	36	5.76
>=8% (>=64 mmol/mol)	59	(4.6)	85	9.78	60	(4.7)	75	8.44
Missing	0				0			
Recovered/resolved								
<8% (<64 mmol/mol)	468	(52.9)	1134	189.67	455	(50.5)	1180	193.72
>=8% (>=64 mmol/mol)	654	(50.9)	1599	166.88	584	(46.0)	1510	163.73
Missing	0				0			
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.7.42 Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
<8% (<64 mmol/mol)	699				708			
>=8% (>=64 mmol/mol)	1181				1169			
Missing	0				1			
PYE (years)								
<8% (<64 mmol/mol)	557.73				565.93			
>=8% (>=64 mmol/mol)	981.19				970.20			
Missing	0.00				0.33			
Events								
<8% (<64 mmol/mol)	419	(60.1)	1294	246.05	404	(56.8)	1284	237.98
>=8% (>=64 mmol/mol)	720	(60.9)	2184	235.01	669	(57.3)	1975	213.92
Missing	0				0			
Serious								
Yes								
<8% (<64 mmol/mol)	56	(8.0)	77	14.22	54	(7.6)	75	12.80
>=8% (>=64 mmol/mol)	99	(8.4)	153	16.25	108	(9.2)	154	16.06
Missing	0				0			
No								
<8% (<64 mmol/mol)	409	(58.7)	1217	231.83	394	(55.4)	1209	225.18
>=8% (>=64 mmol/mol)	693	(58.6)	2031	218.76	642	(55.0)	1821	197.87
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Severity								
Severe								
<8% (<64 mmol/mol)	26	(3.7)	32	6.05	24	(3.4)	34	5.87
>=8% (>=64 mmol/mol)	57	(4.8)	79	8.87	61	(5.2)	94	9.15
Missing	0				0			
Moderate								
<8% (<64 mmol/mol)	162	(23.3)	295	54.81	148	(20.8)	286	50.81
>=8% (>=64 mmol/mol)	299	(25.3)	546	57.07	279	(23.9)	481	51.20
Missing	0				0			
Mild								
<8% (<64 mmol/mol)	352	(50.6)	967	185.20	350	(49.2)	964	181.30
>=8% (>=64 mmol/mol)	592	(50.1)	1559	169.07	553	(47.4)	1400	153.57
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	20	(2.9)	34	6.25	27	(3.8)	40	7.79
>=8% (>=64 mmol/mol)	45	(3.8)	66	8.08	42	(3.6)	85	8.84
Missing	0				0			
Possible								
<8% (<64 mmol/mol)	48	(6.9)	72	15.06	36	(5.1)	70	14.14
>=8% (>=64 mmol/mol)	55	(4.6)	81	9.39	52	(4.5)	67	7.46
Missing	0				0			
Unlikely								
<8% (<64 mmol/mol)	406	(58.3)	1182	223.40	391	(55.0)	1170	215.38
>=8% (>=64 mmol/mol)	692	(58.5)	2031	216.74	646	(55.3)	1821	197.32
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	4	(0.6)	6	1.34	4	(0.6)	4	0.66
>=8% (>=64 mmol/mol)	4	(0.3)	6	0.81	2	(0.2)	2	0.29
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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	5	(0.7)	5	1.22	3	(0.4)	4	0.99
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.89	4	(0.3)	4	0.59
Missing	0				0			
No								
<8% (<64 mmol/mol)	417	(59.9)	1283	243.49	400	(56.3)	1275	236.09
>=8% (>=64 mmol/mol)	719	(60.8)	2171	233.17	668	(57.2)	1968	212.89
Missing	0				0			
NA								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	4	(0.6)	6	1.34	4	(0.6)	4	0.66
>=8% (>=64 mmol/mol)	4	(0.3)	6	0.81	3	(0.3)	3	0.44
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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Outcome								
Fatal								
<8% (<64 mmol/mol)	3	(0.4)	4	0.76	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	10	(0.8)	13	1.54	12	(1.0)	14	1.42
Missing	0				0			
Not recovered/not resolved								
<8% (<64 mmol/mol)	178	(25.6)	328	59.91	170	(23.9)	324	59.25
>=8% (>=64 mmol/mol)	325	(27.5)	625	65.89	317	(27.2)	574	60.23
Missing	0				0			
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	5	(0.7)	5	0.85	5	(0.7)	6	1.04
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	8	(0.7)	9	0.90
Missing	0				0			
Recovering/resolving								
<8% (<64 mmol/mol)	34	(4.9)	48	9.44	30	(4.2)	34	6.74
>=8% (>=64 mmol/mol)	56	(4.8)	82	10.11	57	(4.9)	69	8.14
Missing	0				0			
Recovered/resolved								
<8% (<64 mmol/mol)	364	(52.3)	909	175.09	349	(49.0)	919	170.81
>=8% (>=64 mmol/mol)	598	(50.5)	1458	156.91	529	(45.4)	1307	143.07
Missing	0				0			
Unknown								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Missing	0				0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.7.43 Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main- on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
<8% (<64 mmol/mol)	888				897			
>=8% (>=64 mmol/mol)	1282				1272			
Missing	0				1			
PYE (years)								
<8% (<64 mmol/mol)	649.98				659.50			
>=8% (>=64 mmol/mol)	1031.26				1020.75			
Missing	0.00				0.33			
Events								
<8% (<64 mmol/mol)	540	(61.0)	1606	265.58	528	(58.7)	1647	269.76
>=8% (>=64 mmol/mol)	788	(61.4)	2379	247.36	735	(57.9)	2231	237.29
Missing	0				0			
Infections and infestations								
All								
<8% (<64 mmol/mol)	252	(28.5)	340	58.23	266	(29.5)	386	63.93
>=8% (>=64 mmol/mol)	396	(30.9)	580	61.97	358	(28.2)	519	53.74
COVID-19								
<8% (<64 mmol/mol)	61	(6.9)	62	10.84	69	(7.7)	71	11.83
>=8% (>=64 mmol/mol)	120	(9.3)	123	12.69	123	(9.7)	128	12.61
Nasopharyngitis								
<8% (<64 mmol/mol)	51	(5.8)	58	10.62	54	(6.0)	67	12.82
>=8% (>=64 mmol/mol)	66	(5.2)	83	9.72	61	(4.8)	68	7.44
Upper respiratory tract infection								
<8% (<64 mmol/mol)	27	(3.1)	32	4.88	18	(2.0)	21	3.03
>=8% (>=64 mmol/mol)	41	(3.2)	49	4.88	34	(2.7)	35	3.89
Urinary tract infection								
<8% (<64 mmol/mol)	13	(1.5)	13	2.07	20	(2.2)	25	3.76
>=8% (>=64 mmol/mol)	30	(2.4)	33	3.74	30	(2.4)	31	3.15
Influenza								
<8% (<64 mmol/mol)	8	(0.9)	10	1.90	12	(1.3)	14	2.69
>=8% (>=64 mmol/mol)	21	(1.7)	22	2.66	21	(1.6)	22	2.69
Gastroenteritis								
<8% (<64 mmol/mol)	15	(1.7)	16	3.17	8	(0.9)	9	1.52
>=8% (>=64 mmol/mol)	17	(1.3)	17	1.96	10	(0.8)	10	1.21
Bronchitis								
<8% (<64 mmol/mol)	15	(1.7)	15	2.58	10	(1.1)	10	1.51
>=8% (>=64 mmol/mol)	15	(1.2)	16	1.67	9	(0.7)	9	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sinusitis								
<8% (<64 mmol/mol)	6	(0.7)	6	1.23	11	(1.2)	11	1.82
>=8% (>=64 mmol/mol)	13	(1.0)	15	1.53	8	(0.6)	11	1.01
COVID-19 pneumonia								
<8% (<64 mmol/mol)	4	(0.5)	4	0.53	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	11	(0.9)	11	1.22	8	(0.6)	8	0.81
Pharyngitis								
<8% (<64 mmol/mol)	10	(1.2)	11	1.63	8	(0.9)	9	1.35
>=8% (>=64 mmol/mol)	11	(0.9)	12	1.33	10	(0.8)	12	1.26
Tooth infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	6	(0.7)	6	0.99
>=8% (>=64 mmol/mol)	8	(0.6)	10	1.00	2	(0.2)	2	0.27
Tooth abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	5	(0.5)	6	0.90
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.93	2	(0.2)	2	0.15
Pneumonia								
<8% (<64 mmol/mol)	8	(0.9)	8	1.23	4	(0.4)	4	0.61
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.80	2	(0.2)	2	0.21
Herpes zoster								
<8% (<64 mmol/mol)	4	(0.5)	4	0.55	6	(0.7)	6	0.97
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.68	11	(0.9)	12	1.11
Cystitis								
<8% (<64 mmol/mol)	8	(0.9)	8	1.41	11	(1.2)	12	1.67
>=8% (>=64 mmol/mol)	7	(0.5)	8	0.85	6	(0.5)	7	0.78
Rhinitis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.68	9	(0.7)	12	1.47
Viral infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	5	(0.6)	5	0.98
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.60	8	(0.6)	11	0.93
Lower respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.54	2	(0.2)	4	0.33
Otitis media								
<8% (<64 mmol/mol)	2	(0.2)	2	0.37	2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.56	3	(0.2)	3	0.35
Respiratory tract infection								
<8% (<64 mmol/mol)	4	(0.5)	4	0.66	3	(0.3)	3	0.32
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.50	3	(0.2)	3	0.36

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Respiratory tract infection viral								
<8% (<64 mmol/mol)	7	(0.8)	7	1.36	6	(0.7)	6	1.06
>=8% (>=64 mmol/mol)	5	(0.4)	6	0.72	4	(0.3)	5	0.69
Conjunctivitis								
<8% (<64 mmol/mol)	7	(0.8)	7	1.30	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.47	4	(0.3)	4	0.43
Acute sinusitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	4	(0.5)	4	0.76
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	2	(0.2)	2	0.23
Gastroenteritis viral								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	4	(0.3)	4	0.37
Fungal infection								
<8% (<64 mmol/mol)	4	(0.5)	5	0.72	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	1	(0.1)	1	0.08
Vaginal infection								
<8% (<64 mmol/mol)	3	(0.3)	4	0.75	2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	1	(0.1)	1	0.13
Wound infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	0			
Ear infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	2	(0.2)	2	0.15
Cellulitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	5	(0.4)	6	0.70
Coronavirus infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	4	(0.4)	5	0.66
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	1	(0.1)	2	0.28
Gingivitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	3	(0.2)	4	0.39	4	(0.3)	4	0.49
Vulvovaginal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	4	0.36	4	(0.3)	4	0.33
Laryngitis								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	3	(0.2)	3	0.35

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	2	(0.2)	3	0.68
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	3	(0.2)	4	0.31
Otitis externa								
<8% (<64 mmol/mol)	0				3	(0.3)	3	0.56
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	3	(0.2)	3	0.31
Abscess limb								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.45
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.13
Vulvitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	0			
Tinea cruris								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	0			
Tonsillitis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	2	(0.2)	2	0.22
Helicobacter infection								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Oral herpes								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.41	0			
Sepsis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	0			
Acarodermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	3	(0.2)	3	0.23
Furuncle								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.29	2	(0.2)	2	0.16
Genital infection fungal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.40	1	(0.1)	1	0.07
Osteomyelitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Candida infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Hordeolum								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.16
Erysipelas								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	2	(0.2)	3	0.34
Genital candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Genital infection								
<8% (<64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Injection site abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Oral candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Postoperative wound infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.07
Norovirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Severe acute respiratory syndrome								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Vulvovaginitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Anal abscess								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Fungal skin infection								
<8% (<64 mmol/mol)	2	(0.2)	2	0.34	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Kidney infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Paraspinal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Pulpitis dental								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	3	(0.2)	3	0.35
Pustule								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Appendicitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Chronic sinusitis								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Clostridium difficile colitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Ear infection fungal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Gangrene								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nail infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	1	(0.1)	1	0.08
Paronychia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	2	0.28
Post-acute COVID-19 syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	0			
Pyelonephritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Subcutaneous abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	3	0.24
Viral pharyngitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diabetic foot infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.07
Periodontitis								
<8% (<64 mmol/mol)	4	(0.5)	4	0.66	6	(0.7)	6	0.94
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.13
Pneumonia viral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Pulmonary tuberculoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Balanitis candida								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Chlamydial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Chronic tonsillitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Dermatophytosis of nail								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Herpes simplex								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Herpes virus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Infected bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Localised infection								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16
Mastitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Onychomycosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Oropharyngeal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Otitis media chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tinea infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Urethritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Viral upper respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Abdominal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bacteraemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bacterial infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bartholinitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Body tinea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Breast abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Breast cellulitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Campylobacter gastroenteritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Cholecystitis infective								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Chronic hepatitis C								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Clostridium difficile infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cystitis escherichia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Diverticulitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.32
Empyema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Endophthalmitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Enteritis infectious								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Epididymitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Escherichia bacteraemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Escherichia urinary tract infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Eye infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Eye infection bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Folliculitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.22
Fungal balanitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Gastric infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Gastroenteritis norovirus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Giardiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Helicobacter gastritis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Herpes dermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Herpes zoster infection neurological								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Infected cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Infected dermal cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Infective iritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Labyrinthitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Laryngopharyngitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.15
Lyme disease								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Oophoritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Otitis media acute								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Parotitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Peri-implantitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Pericoronitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Peritonsillar abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pharyngotonsillitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	2	0.21
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Post procedural infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Purulence								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory syncytial virus infection								
<8% (<64 mmol/mol)	3	(0.3)	3	0.42	0			
>=8% (>=64 mmol/mol)	0				0			
Rotavirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Salpingitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Sinusitis bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Skin bacterial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Skin candida								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Skin infection								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Soft tissue infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Suspected COVID-19								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Sweat gland infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tinea pedis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	0				0			
Tinea versicolour								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Tracheitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Urosepsis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Varicella								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Varicella zoster virus infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Viral rhinitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Viral tracheitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	122	(13.8)	163	26.07	103	(11.4)	141	22.06
>=8% (>=64 mmol/mol)	155	(12.1)	255	25.72	142	(11.2)	202	21.96
Diarrhoea								
<8% (<64 mmol/mol)	44	(5.0)	47	7.04	23	(2.5)	24	3.51
>=8% (>=64 mmol/mol)	45	(3.5)	61	6.40	32	(2.5)	33	3.81
Nausea								
<8% (<64 mmol/mol)	16	(1.8)	17	2.60	14	(1.6)	14	2.48
>=8% (>=64 mmol/mol)	25	(1.9)	25	2.58	21	(1.6)	23	2.47
Vomiting								
<8% (<64 mmol/mol)	15	(1.7)	15	2.92	12	(1.3)	12	2.06
>=8% (>=64 mmol/mol)	16	(1.3)	24	2.72	9	(0.7)	12	1.19
Abdominal pain								
<8% (<64 mmol/mol)	5	(0.6)	5	0.92	6	(0.7)	7	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	12	(0.9)	12	1.10	12	(0.9)	12	1.29
Constipation								
<8% (<64 mmol/mol)	6	(0.7)	7	1.17	6	(0.7)	6	0.91
>=8% (>=64 mmol/mol)	11	(0.9)	13	1.37	10	(0.8)	10	1.12
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	4	(0.5)	4	0.73	8	(0.9)	8	1.15
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.89	7	(0.6)	7	0.78
Toothache								
<8% (<64 mmol/mol)	5	(0.6)	5	0.77	5	(0.6)	6	1.19
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.91	8	(0.6)	12	1.60
Abdominal pain upper								
<8% (<64 mmol/mol)	7	(0.8)	9	1.49	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.91	13	(1.0)	14	1.40
Dental caries								
<8% (<64 mmol/mol)	4	(0.5)	5	0.60	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	8	(0.6)	9	0.77	7	(0.5)	7	0.83
Abdominal distension								
<8% (<64 mmol/mol)	0				3	(0.3)	3	0.44
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.76	2	(0.2)	2	0.28
Chronic gastritis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.71	4	(0.3)	4	0.46
Haemorrhoids								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	3	(0.3)	3	0.53
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	1	(0.1)	1	0.13
Food poisoning								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	4	(0.4)	5	0.88
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	0			
Gastritis								
<8% (<64 mmol/mol)	5	(0.6)	5	0.82	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	6	(0.5)	6	0.57
Dyspepsia								
<8% (<64 mmol/mol)	5	(0.6)	5	0.75	2	(0.2)	2	0.31
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.40	7	(0.5)	7	0.74
Large intestine polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	4	0.52
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	3	(0.2)	3	0.23
Abdominal discomfort								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	4	0.69
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.37	3	(0.2)	3	0.31

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Anal fissure								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	1	(0.1)	1	0.07
Hiatus hernia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Diverticulum intestinal								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Hypoaesthesia oral								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	2	(0.2)	4	0.49	0			
Flatulence								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Abdominal pain lower								
<8% (<64 mmol/mol)	2	(0.2)	2	0.37	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Rectal polyp								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Noninfective gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Oral pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Vomiting projectile								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Pancreatic failure								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Diverticulum								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	2	(0.2)	2	0.21
Gastrointestinal angiodysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Gingival bleeding								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Aphthous ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis microscopic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Diabetic gastropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eructation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Gastric ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Impaired gastric emptying								
<8% (<64 mmol/mol)	1	(0.1)	2	0.46	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Intestinal dilatation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Umbilical hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Pancreatitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.08
Anal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis ischaemic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Enterocolitis								
<8% (<64 mmol/mol)	2	(0.2)	3	0.36	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Frequent bowel movements								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Haematochezia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hyperaesthesia teeth								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Loose tooth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Oral discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pancreatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.27
Tooth disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tooth impacted								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Abdominal wall disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Acid peptic disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Crohn's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Dry mouth								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.11

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Duodenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Enteritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Eosinophilic oesophagitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Epigastric discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Faeces pale								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Faeces soft								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Gastric dilatation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Gastric disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Gastric dysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Gastric mucosal hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Gastric polyps								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.37
Gastritis erosive								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal sounds abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Gingival disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Gingival recession								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.32
Haemorrhoidal haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Hyperchlorhydria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Ileus								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	0				0			
Inguinal hernia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.21	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16
Intra-abdominal haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Irritable bowel syndrome								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Lip swelling								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Lumbar hernia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Melaena								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Mesenteric panniculitis								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Odynophagia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Oesophageal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Oesophagitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Pancreatic duct dilatation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatic pseudocyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Pancreatitis acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Peptic ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Periodontal inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.21
>=8% (>=64 mmol/mol)	0				0			
Pneumatosis intestinalis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Proctalgia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Rectal prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Small intestinal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Stomatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tongue rough								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Ulcerative gastritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Upper gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	120	(13.6)	182	28.35	111	(12.3)	153	24.81
>=8% (>=64 mmol/mol)	153	(11.9)	218	21.87	173	(13.7)	248	26.73
Back pain								
<8% (<64 mmol/mol)	29	(3.3)	31	4.87	28	(3.1)	31	5.41
>=8% (>=64 mmol/mol)	36	(2.8)	38	3.73	44	(3.5)	58	6.96
Arthralgia								
<8% (<64 mmol/mol)	27	(3.1)	33	5.01	27	(3.0)	29	4.67
>=8% (>=64 mmol/mol)	24	(1.9)	26	2.77	30	(2.4)	34	3.81
Pain in extremity								
<8% (<64 mmol/mol)	13	(1.5)	13	2.21	21	(2.4)	24	4.31
>=8% (>=64 mmol/mol)	24	(1.9)	26	2.37	16	(1.3)	19	1.94
Muscle spasms								
<8% (<64 mmol/mol)	10	(1.1)	10	1.70	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	15	(1.2)	17	1.85	6	(0.5)	6	0.59
Osteoarthritis								
<8% (<64 mmol/mol)	11	(1.3)	12	2.02	8	(0.9)	11	1.73
>=8% (>=64 mmol/mol)	13	(1.0)	14	1.28	18	(1.4)	18	1.79
Myalgia								
<8% (<64 mmol/mol)	9	(1.0)	9	1.49	6	(0.7)	6	1.09
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.83	10	(0.8)	11	1.49
Neck pain								
<8% (<64 mmol/mol)	9	(1.0)	9	1.60	5	(0.5)	5	0.71
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.60	3	(0.2)	3	0.25
Tendonitis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	3	(0.3)	3	0.53
>=8% (>=64 mmol/mol)	6	(0.5)	8	0.78	2	(0.2)	2	0.22
Periarthritis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	3	(0.3)	3	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.52	6	(0.5)	6	0.69
Arthritis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	3	(0.3)	3	0.49
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.52	3	(0.2)	3	0.35
Trigger finger								
<8% (<64 mmol/mol)	4	(0.5)	4	0.77	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.62	5	(0.4)	7	0.61
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.42	0			
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	4	(0.5)	8	0.98	1	(0.1)	2	0.21
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.36	5	(0.4)	5	0.50
Muscular weakness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.43	3	(0.2)	3	0.35
Exostosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Intervertebral disc disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	1	(0.1)	1	0.13
Plantar fasciitis								
<8% (<64 mmol/mol)	1	(0.1)	2	0.24	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	3	(0.2)	3	0.23
Rotator cuff syndrome								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	3	(0.2)	3	0.22
Osteoporosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	0			
Bursitis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	2	(0.2)	2	0.16
Musculoskeletal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Musculoskeletal chest pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.07

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Back disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Fibromyalgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Groin pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Pain in jaw								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Tendon disorder								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Torticollis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Limb discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Tenosynovitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	4	0.43
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	6	(0.5)	6	0.59
Polymyalgia rheumatica								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	3	0.40
Soft tissue swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	3	0.40	0			
Diastasis recti abdominis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Facet joint syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Foot deformity								
<8% (<64 mmol/mol)	2	(0.2)	3	0.41	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	2	(0.2)	2	0.21
Joint effusion								
<8% (<64 mmol/mol)	1	(0.1)	2	0.38	1	(0.1)	1	0.11

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Psoriatic arthropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal osteoarthritis								
<8% (<64 mmol/mol)	5	(0.6)	5	0.73	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	5	0.37
Osteochondrosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	4	(0.3)	4	0.43
Costochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Polyarthritis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.30
Spinal stenosis								
<8% (<64 mmol/mol)	3	(0.3)	5	0.87	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Synovial cyst								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Acquired claw toe								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Arthropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Axillary mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bone cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Bone pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cervical spinal stenosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Chondromalacia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Chondropathy								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Coccydynia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Dupuytren's contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Fistula								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Flank pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				5	(0.4)	6	0.58
Haemarthrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Intervertebral disc degeneration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Intervertebral disc space narrowing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.15
Jaw disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Joint swelling								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Limb deformity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Limb mass								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Lumbar spinal stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Mastication disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16
Meniscopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Muscle contracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Muscle twitching								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Myositis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Neuropathic arthropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Nodal osteoarthritis								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	0				0			
Osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Osteopenia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Periostitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Rheumatoid arthritis								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Sacroiliitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Scoliosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Spinal retrolisthesis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.15
Tenosynovitis stenosans								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vertebral osteophyte								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	101	(11.4)	144	24.98	109	(12.0)	198	33.22
>=8% (>=64 mmol/mol)	139	(10.8)	219	23.90	99	(7.8)	146	15.12
Fatigue								
<8% (<64 mmol/mol)	10	(1.1)	13	2.25	9	(1.0)	9	1.09
>=8% (>=64 mmol/mol)	22	(1.7)	23	2.34	7	(0.5)	7	0.77
Pyrexia								
<8% (<64 mmol/mol)	19	(2.1)	20	3.70	21	(2.3)	21	3.34
>=8% (>=64 mmol/mol)	22	(1.7)	23	2.25	22	(1.7)	24	2.54
Oedema peripheral								
<8% (<64 mmol/mol)	3	(0.3)	3	0.45	4	(0.4)	4	0.60
>=8% (>=64 mmol/mol)	16	(1.3)	16	1.78	6	(0.5)	7	0.64
Chest pain								
<8% (<64 mmol/mol)	3	(0.3)	3	0.33	3	(0.3)	3	0.44
>=8% (>=64 mmol/mol)	11	(0.9)	11	1.14	4	(0.3)	4	0.39
Injection site reaction								
<8% (<64 mmol/mol)	6	(0.7)	15	2.75	4	(0.5)	6	0.91
>=8% (>=64 mmol/mol)	9	(0.7)	14	1.84	2	(0.2)	2	0.16
Malaise								
<8% (<64 mmol/mol)	7	(0.8)	8	1.24	9	(1.0)	50	10.39
>=8% (>=64 mmol/mol)	9	(0.7)	10	1.02	6	(0.5)	10	1.24
Pain								
<8% (<64 mmol/mol)	5	(0.6)	6	1.23	6	(0.7)	6	0.82
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.87	8	(0.6)	9	0.93
Asthenia								
<8% (<64 mmol/mol)	3	(0.3)	3	0.50	9	(1.0)	9	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.72	1	(0.1)	1	0.16
Medical device site bruise								
<8% (<64 mmol/mol)	1	(0.1)	2	0.37	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.70	0			
Vaccination site pain								
<8% (<64 mmol/mol)	4	(0.5)	5	0.81	4	(0.4)	4	0.52
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.77	5	(0.4)	5	0.70
Chest discomfort								
<8% (<64 mmol/mol)	3	(0.3)	3	0.41	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.56	0			
Peripheral swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	5	(0.4)	6	0.58	3	(0.2)	3	0.35
Injection site pain								
<8% (<64 mmol/mol)	0				7	(0.8)	7	1.22
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.41	6	(0.5)	24	1.98
Influenza like illness								
<8% (<64 mmol/mol)	4	(0.4)	5	0.90	2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.41	2	(0.2)	2	0.16
Injection site pruritus								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	3	(0.2)	18	2.39	0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	4	(0.5)	4	0.77	6	(0.6)	12	1.41
>=8% (>=64 mmol/mol)	3	(0.2)	6	0.60	5	(0.4)	6	0.72
Medical device site reaction								
<8% (<64 mmol/mol)	4	(0.4)	4	0.88	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	5	0.50	0			
Chills								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	0			
Drug intolerance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	0			
Injection site bruising								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	2	(0.2)	2	0.16
Injection site haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	2	(0.2)	2	0.21

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Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Medical device site rash								
<8% (<64 mmol/mol)	4	(0.4)	4	0.92	4	(0.4)	4	0.91
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.32	4	(0.3)	4	0.61
Injection site erythema								
<8% (<64 mmol/mol)	1	(0.1)	3	0.57	3	(0.3)	3	0.32
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Thirst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Gait disturbance								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Injection site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Medical device site pruritus								
<8% (<64 mmol/mol)	3	(0.3)	3	0.54	4	(0.4)	4	0.79
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Application site bruise								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Application site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Discomfort								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	8	1.54
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Inflammation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	2	(0.2)	2	0.16
Injection site haematoma								
<8% (<64 mmol/mol)	1	(0.1)	4	0.76	1	(0.1)	5	0.98
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.27	2	(0.2)	3	0.40
Injection site swelling								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.13
Hunger								
<8% (<64 mmol/mol)	6	(0.7)	7	0.90	3	(0.3)	4	0.75
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Medical device site haematoma								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	1	(0.1)	1	0.08
Medical device site erythema								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	4	(0.4)	4	0.75
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	2	0.32
Early satiety								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injection site mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16
Localised oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Multiple organ dysfunction syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Oedema								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.07
Vaccination site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Vaccination site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Feeling hot								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Implant site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injection site dermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site eczema								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site haemorrhage								
<8% (<64 mmol/mol)	3	(0.4)	3	0.36	2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Medical device site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	2	(0.2)	2	0.33
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Axillary pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Condition aggravated								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Cyst								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Death								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.23
Facial pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Feeling abnormal								
<8% (<64 mmol/mol)	3	(0.3)	5	0.75	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Hernia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Hyperthermia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Injection site hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Injection site induration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Injection site oedema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Injection site rash								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Injection site urticaria								
<8% (<64 mmol/mol)	1	(0.1)	2	0.46	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Medical device site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Medical device site irritation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Non-cardiac chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				4	(0.3)	6	0.46
Oedema due to renal disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Procedural failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Swelling face								
<8% (<64 mmol/mol)	2	(0.2)	2	0.34	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Systemic inflammatory response syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Vaccination site erythema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Vaccination site reaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Vessel puncture site bruise								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Xerosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nervous system disorders								
All								
<8% (<64 mmol/mol)	93	(10.5)	134	22.49	91	(10.1)	134	22.13
>=8% (>=64 mmol/mol)	114	(8.9)	164	17.57	116	(9.1)	192	22.58
Headache								
<8% (<64 mmol/mol)	34	(3.8)	45	8.22	33	(3.6)	45	7.01
>=8% (>=64 mmol/mol)	36	(2.8)	47	5.36	31	(2.4)	35	4.04
Dizziness								
<8% (<64 mmol/mol)	21	(2.4)	29	4.80	15	(1.7)	19	3.44
>=8% (>=64 mmol/mol)	19	(1.5)	22	2.03	24	(1.9)	28	2.84
Sciatica								
<8% (<64 mmol/mol)	4	(0.4)	4	0.67	5	(0.5)	5	0.71
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.93	7	(0.6)	8	0.74
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	3	(0.3)	3	0.49	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.73	7	(0.6)	7	0.81
Paraesthesia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	7	(0.8)	7	1.10
>=8% (>=64 mmol/mol)	7	(0.5)	8	0.67	5	(0.4)	5	0.55
Syncope								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.60	1	(0.1)	1	0.08
Diabetic neuropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.59	9	(0.7)	9	0.93
Hypoaesthesia								
<8% (<64 mmol/mol)	4	(0.5)	7	1.04	6	(0.7)	6	1.03
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.50	4	(0.3)	5	0.45
Migraine								
<8% (<64 mmol/mol)	4	(0.4)	5	1.06	3	(0.3)	3	0.65
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	2	(0.2)	2	0.22
Neuropathy peripheral								
<8% (<64 mmol/mol)	3	(0.3)	3	0.50	5	(0.6)	5	0.72
>=8% (>=64 mmol/mol)	3	(0.2)	4	0.43	5	(0.4)	5	0.52
Tremor								
<8% (<64 mmol/mol)	9	(1.0)	10	1.41	4	(0.4)	8	1.58
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	6	(0.5)	53	8.14
Amnesia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			

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	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cervicobrachial syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.07
Disturbance in attention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	10	1.51	0			
Neuralgia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Dysgeusia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Vascular headache								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Hypoglycaemic seizure								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Loss of consciousness								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	1	(0.1)	1	0.07
Sinus headache								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	1	(0.1)	1	0.16
Carotid artery aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Peripheral paralysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Piriformis syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Thalamic infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Carotid artery stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Intracranial pressure increased								

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	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cerebral arteriosclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Cerebrovascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Memory impairment								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Vascular encephalopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Ageusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Anosmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Balance disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Burning sensation								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.22
Dizziness postural								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lumbar radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	5	0.40
Neuroglycopenia								
<8% (<64 mmol/mol)	0				1	(0.1)	3	0.32
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tension headache								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	0			

%: Percentage of subjects with one or more events, E: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Trigeminal neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Autonomic nervous system imbalance								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	0			
>=8% (>=64 mmol/mol)	0				0			
Basilar migraine								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Brain injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Carotid arteriosclerosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Cerebral artery embolism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Cerebral atrophy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Cerebral haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Cerebral infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Cerebrovascular accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Cervical radiculopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Cluster headache								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Cognitive disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Dementia Alzheimer's type								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Encephalopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Essential tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Facial nerve disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Facial paralysis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Haemorrhage intracranial								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Hemiparesis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic coma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic unconsciousness								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Hyporeflexia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Hypotonia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Ischaemic stroke								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Lethargy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Mental impairment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Meralgia paraesthetica								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Morton's neuralgia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Myelopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Ophthalmic migraine								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Orthostatic tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Parkinsonian gait								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Presyncope								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.31
Radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Restless legs syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Sleep deficit								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Somnolence								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Speech disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Thrombotic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.22
Transient ischaemic attack								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	3	(0.3)	3	0.41	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	0				0			
Vertebral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
White matter lesion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Eye disorders								
All								
<8% (<64 mmol/mol)	64	(7.2)	87	15.58	78	(8.7)	110	19.07
>=8% (>=64 mmol/mol)	112	(8.8)	138	15.10	102	(8.0)	126	14.36
Diabetic retinopathy								
<8% (<64 mmol/mol)	22	(2.5)	23	4.32	28	(3.1)	28	5.11
>=8% (>=64 mmol/mol)	42	(3.3)	47	5.74	44	(3.4)	48	5.65
Cataract								
<8% (<64 mmol/mol)	5	(0.6)	6	0.98	13	(1.5)	14	1.93
>=8% (>=64 mmol/mol)	23	(1.8)	27	2.65	14	(1.1)	16	1.76
Macular oedema								
<8% (<64 mmol/mol)	4	(0.5)	5	1.00	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.99	3	(0.2)	3	0.22
Dry eye								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	4	(0.4)	4	0.55
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.52	3	(0.2)	3	0.30
Vision blurred								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.58	4	(0.3)	4	0.43
Diabetic retinal oedema								
<8% (<64 mmol/mol)	3	(0.3)	3	0.61	3	(0.3)	3	0.53
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.43	7	(0.5)	8	0.91
Blepharitis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.24	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	0			
Eye pain								
<8% (<64 mmol/mol)	2	(0.2)	2	0.21	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	3	(0.2)	3	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Retinopathy hypertensive								
<8% (<64 mmol/mol)	6	(0.7)	6	1.14	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.29	4	(0.3)	4	0.49
Glaucoma								
<8% (<64 mmol/mol)	2	(0.2)	2	0.21	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	4	(0.3)	4	0.56
Retinal haemorrhage								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Conjunctivitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.29	0			
Ocular hyperaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	2	0.39
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.27	0			
Cataract nuclear								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Epiretinal membrane								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	2	(0.2)	2	0.31
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.16
Lacrimation increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Retinal exudates								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Retinal vein occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Amaurosis fugax								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Arteriosclerotic retinopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Conjunctival suffusion								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Maculopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Retinal degeneration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Visual impairment								
<8% (<64 mmol/mol)	0				2	(0.2)	10	1.84
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Presbyopia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	2	(0.2)	2	0.29
Retinal deposits								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Asthenopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Astigmatism								
<8% (<64 mmol/mol)	1	(0.1)	2	0.21	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.37
Conjunctival erosion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diplopia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eye inflammation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Posterior capsule opacification								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Retinal tear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acquired epiblepharon								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Angle closure glaucoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Chorioretinal atrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Conjunctival hyperaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Corneal bleeding								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Corneal erosion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Cystoid macular oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Dacryoadenitis acquired								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Dry age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Eye discharge								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Eye irritation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Eye pruritus								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.39
>=8% (>=64 mmol/mol)	0				0			
Eyelid oedema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Hypermetropia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Macular degeneration								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Macular hole								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Meibomianitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Myopia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.31
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	3	(0.3)	4	0.84	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Normal tension glaucoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Ocular hypertension								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	2	(0.2)	3	0.56
>=8% (>=64 mmol/mol)	0				0			
Ocular ischaemic syndrome								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Open angle glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.28
Ophthalmic vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Optic disc haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Optic disc vascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Photophobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Photopsia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Post thrombotic retinopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Pterygium								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Retinal aneurysm								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Retinal artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Retinal detachment								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Retinal drusen								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Retinal scar								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal vascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Retinopathy								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	0				0			
Scintillating scotoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Uveitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Visual acuity reduced								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Vitreous degeneration								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Vitreous floaters								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Vitreous haemorrhage								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vitreous opacities								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	82	(9.3)	106	17.45	80	(8.9)	96	16.63
>=8% (>=64 mmol/mol)	112	(8.7)	135	14.49	100	(7.9)	121	13.42
Fall								
<8% (<64 mmol/mol)	9	(1.0)	9	1.31	4	(0.4)	4	0.72
>=8% (>=64 mmol/mol)	11	(0.9)	11	1.04	7	(0.5)	8	0.72
Ligament sprain								
<8% (<64 mmol/mol)	3	(0.3)	3	0.43	4	(0.5)	4	0.69
>=8% (>=64 mmol/mol)	9	(0.7)	9	1.17	4	(0.3)	4	0.43
Contusion								
<8% (<64 mmol/mol)	6	(0.7)	7	1.16	6	(0.7)	6	0.88
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.81	3	(0.2)	3	0.29
Vaccination complication								
<8% (<64 mmol/mol)	11	(1.3)	15	2.67	16	(1.8)	19	3.25
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.92	13	(1.0)	19	2.05
Accidental overdose								
<8% (<64 mmol/mol)	7	(0.8)	7	1.36	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	7	(0.5)	8	1.15	2	(0.2)	3	0.41
Road traffic accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(0.4)	6	0.74	1	(0.1)	1	0.07
Incorrect dose administered								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.73	4	(0.3)	6	0.75
Skin abrasion								
<8% (<64 mmol/mol)	4	(0.5)	7	1.02	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.62	3	(0.2)	3	0.35

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Limb injury								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	3	(0.2)	4	0.54
Upper limb fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	0			
Procedural pain								
<8% (<64 mmol/mol)	2	(0.2)	2	0.34	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	0			
Thermal burn								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	1	(0.1)	1	0.14
Joint injury								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	5	(0.4)	5	0.52
Medication error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	3	(0.2)	3	0.43
Hand fracture								
<8% (<64 mmol/mol)	5	(0.6)	5	0.76	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	1	(0.1)	1	0.07
Rib fracture								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	4	(0.3)	4	0.36
Tendon rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Arthropod bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	2	(0.2)	2	0.21
Foot fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Radius fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Skin laceration								
<8% (<64 mmol/mol)	5	(0.6)	5	0.81	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Tooth fracture								
<8% (<64 mmol/mol)	2	(0.2)	2	0.39	3	(0.3)	3	0.53

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Fibula fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.16
Wound								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	3	(0.3)	3	0.62
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	3	(0.2)	3	0.35
Gun shot wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Ligament rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.27	0			
Procedural complication								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Face injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Prescribed overdose								
<8% (<64 mmol/mol)	4	(0.4)	4	0.92	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Product dispensing error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Facial bones fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Ankle fracture								
<8% (<64 mmol/mol)	3	(0.3)	3	0.33	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Arthropod sting								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Back injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bone contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.22
Hip fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Inflammation of wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injury of conjunctiva								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Neck injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Penile contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post procedural inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Radiation skin injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal compression fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Accidental underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Extra dose administered								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Wrong product administered								
<8% (<64 mmol/mol)	0				4	(0.4)	4	0.84
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.27	2	(0.2)	2	0.32
Burn oral cavity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Burns first degree								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16
Cervical vertebral fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eye injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Heat illness								
<8% (<64 mmol/mol)	0				2	(0.2)	3	0.41
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Meniscus injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Overdose								
<8% (<64 mmol/mol)	3	(0.3)	3	0.57	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.35
Post procedural fistula								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post procedural hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Scar								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Anaemia postoperative								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Animal bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.29
Animal scratch								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Chillblains								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Clavicle fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Concussion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Corneal abrasion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Craniocerebral injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Crush injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Deafness traumatic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Endotracheal intubation complication								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Epicondylitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Exposure to SARS-CoV-2								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Femoral neck fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Head injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Heat stroke								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Humerus fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Injury								
<8% (<64 mmol/mol)	2	(0.2)	2	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Intentional overdose								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Intentional product use issue								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Lower limb fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Multiple injuries								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Muscle contusion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Muscle injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Muscle strain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	3	0.53
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.22
Nerve injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Periprocedural myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Post procedural complication								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural haematuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Post procedural swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.21
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Post-traumatic neck syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Product administration error								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Scratch								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Seroma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Soft tissue injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Spinal column injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Stab wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Subcutaneous haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Subdural haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Sunburn								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Tendon injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Tibia fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Traumatic haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Underdose								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.35
Wound dehiscence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Wrong dose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	46	(5.2)	57	8.61	54	(6.0)	64	10.13
>=8% (>=64 mmol/mol)	86	(6.7)	106	10.34	80	(6.3)	105	10.56
Dyslipidaemia								
<8% (<64 mmol/mol)	8	(0.9)	8	1.09	7	(0.8)	7	1.19
>=8% (>=64 mmol/mol)	13	(1.0)	14	1.55	10	(0.8)	10	1.13
Vitamin D deficiency								
<8% (<64 mmol/mol)	5	(0.6)	5	0.68	7	(0.8)	7	1.05
>=8% (>=64 mmol/mol)	12	(0.9)	12	0.98	7	(0.5)	7	0.61
Hypoglycaemia								
<8% (<64 mmol/mol)	7	(0.8)	11	2.03	11	(1.2)	13	2.28
>=8% (>=64 mmol/mol)	11	(0.9)	15	1.92	12	(1.0)	27	2.71
Hypertriglyceridaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.81	6	(0.5)	6	0.65
Vitamin B12 deficiency								
<8% (<64 mmol/mol)	4	(0.4)	4	0.42	0			
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.53	1	(0.1)	1	0.07
Hyperlipidaemia								
<8% (<64 mmol/mol)	8	(0.9)	8	1.14	5	(0.6)	5	0.72
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.58	8	(0.6)	8	0.74
Hyperkalaemia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	5	(0.6)	5	0.88
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.66	5	(0.4)	5	0.46
Gout								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.38	5	(0.4)	6	0.46
Hyperglycaemia								
<8% (<64 mmol/mol)	3	(0.3)	3	0.48	3	(0.3)	3	0.49
>=8% (>=64 mmol/mol)	3	(0.2)	4	0.48	11	(0.9)	11	1.23
Hyperuricaemia								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.37	2	(0.2)	2	0.15
Iron deficiency								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	3	(0.2)	3	0.22
Decreased appetite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	5	(0.6)	5	0.63
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	0			
Folate deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Hypercholesterolaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	3	(0.2)	3	0.43
Hypokalaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Dehydration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	2	0.45
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Diabetes mellitus								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diabetes mellitus inadequate control								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypernatraemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Magnesium deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Malnutrition								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Vitamin B complex deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypoalbuminaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyponatraemia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Fluid retention								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Increased appetite								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	3	(0.3)	4	0.69
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.35
Obesity								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.16
Abnormal weight gain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Appetite disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.21
>=8% (>=64 mmol/mol)	0				0			
Electrolyte imbalance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Food craving								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Hyperammonaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Hypercalcaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Insulin resistance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Lactic acidosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Lipomatosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Metabolic acidosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Metabolic disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Zinc deficiency								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	54	(6.1)	68	11.42	53	(5.9)	68	10.78
>=8% (>=64 mmol/mol)	78	(6.1)	109	11.60	69	(5.4)	85	9.57
Cough								
<8% (<64 mmol/mol)	8	(0.9)	9	1.64	10	(1.1)	11	1.80
>=8% (>=64 mmol/mol)	18	(1.4)	20	2.02	18	(1.4)	19	2.20
Oropharyngeal pain								
<8% (<64 mmol/mol)	12	(1.4)	13	2.08	6	(0.7)	6	0.94
>=8% (>=64 mmol/mol)	12	(0.9)	13	1.28	13	(1.0)	15	1.75
Nasal congestion								
<8% (<64 mmol/mol)	2	(0.2)	2	0.24	2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.73	3	(0.2)	3	0.31
Dyspnoea								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	5	(0.5)	6	0.99
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.71	8	(0.6)	8	0.75
Rhinorrhoea								
<8% (<64 mmol/mol)	5	(0.6)	7	1.22	6	(0.7)	6	0.97
>=8% (>=64 mmol/mol)	7	(0.5)	8	0.87	7	(0.5)	7	0.93
Epistaxis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	2	0.39
>=8% (>=64 mmol/mol)	5	(0.4)	9	1.23	1	(0.1)	2	0.16
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	3	(0.3)	3	0.43	0			
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	0			
Productive cough								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.42	3	(0.2)	3	0.45
Sinus congestion								
<8% (<64 mmol/mol)	3	(0.3)	4	0.66	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.37	1	(0.1)	1	0.16

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chronic obstructive pulmonary disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	0			
Respiratory disorder								
<8% (<64 mmol/mol)	6	(0.7)	6	1.20	5	(0.5)	5	0.78
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.28
Asthma								
<8% (<64 mmol/mol)	3	(0.3)	3	0.49	0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.29	1	(0.1)	1	0.14
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	2	(0.2)	2	0.16
Sneezing								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	0			
Emphysema								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Pulmonary fibrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.29	0			
Bronchospasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.13
Hiccups								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Pulmonary congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Nasal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Acute respiratory failure								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Increased viscosity of upper respiratory secretion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Rhinitis allergic								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	4	(0.4)	8	1.16
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.27
Upper respiratory tract inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Nasal septum deviation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Pleurisy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Pulmonary hypertension								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Bronchiectasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Interstitial lung disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Laryngeal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nasal turbinate hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Throat irritation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Acquired diaphragmatic eventration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Acute pulmonary oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Allergic bronchitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Allergic cough								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Aphonia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Bronchial hyperreactivity								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Bronchitis chronic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Dry throat								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Dysphonia								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.39
>=8% (>=64 mmol/mol)	0				0			
Haemoptysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lung disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Nasal dryness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Paranasal cyst								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	0				0			
Paranasal sinus discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Pleural disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Pleural effusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.23
Pleuritic pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pulmonary embolism								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Pulmonary mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Respiratory failure								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Respiratory tract inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Sinus pain								
<8% (<64 mmol/mol)	2	(0.2)	3	0.43	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	61	(6.9)	63	10.81	51	(5.6)	60	9.75
>=8% (>=64 mmol/mol)	62	(4.8)	68	6.81	77	(6.1)	95	10.12
Rash								
<8% (<64 mmol/mol)	6	(0.7)	6	1.10	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	8	(0.6)	8	0.85	10	(0.8)	11	0.98
Alopecia								
<8% (<64 mmol/mol)	3	(0.3)	3	0.54	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.61	2	(0.2)	2	0.21
Pruritus								
<8% (<64 mmol/mol)	3	(0.3)	3	0.48	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	9	(0.7)	9	0.96
Eczema								
<8% (<64 mmol/mol)	5	(0.6)	5	0.73	4	(0.4)	4	0.72
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	3	(0.2)	3	0.35
Dermatitis contact								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	6	(0.7)	6	1.21
>=8% (>=64 mmol/mol)	5	(0.4)	6	0.54	8	(0.6)	8	0.86
Urticaria								
<8% (<64 mmol/mol)	3	(0.3)	3	0.48	5	(0.6)	5	0.78
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.42	7	(0.6)	7	0.68

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dermatitis								
<8% (<64 mmol/mol)	4	(0.5)	4	0.77	3	(0.3)	3	0.53
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.40	4	(0.3)	5	0.50
Skin ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	3	(0.2)	3	0.35
Blister								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.08
Miliaria								
<8% (<64 mmol/mol)	0				3	(0.3)	3	0.32
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	1	(0.1)	1	0.08
Hyperkeratosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.14
Hyperhidrosis								
<8% (<64 mmol/mol)	6	(0.7)	6	0.99	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	3	(0.2)	3	0.29
Dry skin								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	5	(0.4)	5	0.52
Rash erythematous								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Ingrown hair								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Xeroderma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Acne								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diabetic foot								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Erythema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.37
Livedo reticularis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Night sweats								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Intertrigo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Angioedema								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Ingrowing nail								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Lipodystrophy acquired								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Myxoid cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Psoriasis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Skin exfoliation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Skin irritation								
<8% (<64 mmol/mol)	3	(0.3)	3	0.58	2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	1	(0.1)	1	0.07
Skin lesion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.24
Urticaria contact								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Actinic keratosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Alopecia areata								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asteatosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Chronic spontaneous urticaria								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	4	(0.5)	4	0.63	4	(0.4)	4	0.63
>=8% (>=64 mmol/mol)	0				4	(0.3)	8	1.26
Cold urticaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Decubitus ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Dermal cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.46
Dermatitis allergic								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Dermatitis atopic								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	0				0			
Drug eruption								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Ecchymosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Granuloma annulare								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Haemorrhage subcutaneous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hidradenitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Lentigo								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Leukoplakia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Lichen sclerosus								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Lipohypertrophy								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	0				0			
Macule								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Nail bed inflammation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Neurodermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Pruritus allergic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Purpura								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Rash maculo-papular								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Rash papular								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Seborrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Skin discolouration								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Skin fissures								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Skin odour abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Skin reaction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Telangiectasia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Umbilical haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Urticaria thermal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cardiac disorders								
All								
<8% (<64 mmol/mol)	37	(4.2)	51	7.52	38	(4.2)	52	7.39
>=8% (>=64 mmol/mol)	58	(4.5)	82	7.40	46	(3.6)	63	5.97
Coronary artery disease								
<8% (<64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.82	8	(0.6)	8	0.74
Angina pectoris								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.52	1	(0.1)	1	0.08
Myocardial infarction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.64	3	(0.2)	3	0.24
Atrial fibrillation								
<8% (<64 mmol/mol)	7	(0.8)	7	0.92	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.60	5	(0.4)	5	0.47
Acute myocardial infarction								
<8% (<64 mmol/mol)	4	(0.5)	4	0.69	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.38	6	(0.5)	6	0.59
Cardiac failure								
<8% (<64 mmol/mol)	3	(0.3)	3	0.33	2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	1	(0.1)	2	0.28
Acute coronary syndrome								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.31	0			
Palpitations								
<8% (<64 mmol/mol)	3	(0.3)	3	0.54	6	(0.7)	6	0.97
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.31	1	(0.1)	1	0.08
Ventricular extrasystoles								
<8% (<64 mmol/mol)	4	(0.5)	4	0.70	1	(0.1)	2	0.22
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.39	1	(0.1)	1	0.08
Tachycardia								
<8% (<64 mmol/mol)	0				3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	4	(0.3)	4	0.36
Angina unstable								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	2	(0.2)	2	0.24
Supraventricular tachycardia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Myocardial ischaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	3	(0.2)	3	0.31
Cardiac failure congestive								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	2	(0.2)	3	0.58
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Cardio-respiratory arrest								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Mitral valve stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Supraventricular extrasystoles								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.08
Bundle branch block right								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	4	0.55
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	4	(0.3)	4	0.43
Cardiac flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Arteriosclerosis coronary artery								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Atrioventricular block first degree								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	2	(0.2)	2	0.24	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Mitral valve incompetence								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Aortic valve sclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Left atrial enlargement								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.31
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Atrial flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Atrial thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cardiac failure chronic								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Chronic coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Coronary artery occlusion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Left atrial dilatation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pericarditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Tricuspid valve incompetence								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Aortic valve calcification								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Aortic valve incompetence								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Arrhythmia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Atrial enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Atrioventricular block complete								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bradycardia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Bundle branch block left								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Cardiac arrest								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	0				0			
Cardiac dysfunction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Cardiac failure acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Cardiac perfusion defect								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.39
>=8% (>=64 mmol/mol)	0				0			
Cardiac ventricular thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiomegaly								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiovascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Coronary artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Diastolic dysfunction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Left ventricular dysfunction								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Pericardial effusion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Sinus arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Sinus bradycardia								
<8% (<64 mmol/mol)	0				3	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	0				0			
Sinus tachycardia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.23
Subendocardial ischaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Ventricular arrhythmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Ventricular tachycardia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Investigations								
All								
<8% (<64 mmol/mol)	41	(4.6)	49	8.18	32	(3.6)	37	6.68
>=8% (>=64 mmol/mol)	53	(4.1)	60	6.19	47	(3.7)	51	5.15
Weight increased								
<8% (<64 mmol/mol)	4	(0.5)	4	0.61	3	(0.3)	3	0.50
>=8% (>=64 mmol/mol)	16	(1.2)	16	1.67	15	(1.2)	15	1.49
Blood creatinine increased								
<8% (<64 mmol/mol)	3	(0.3)	3	0.48	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.62	0			

%: Percentage of subjects with one or more events, E: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	3	(0.3)	3	0.68
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.56	1	(0.1)	1	0.16
Blood alkaline phosphatase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.41	0			
Blood immunoglobulin E increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	2	(0.2)	2	0.15
Weight decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	1	(0.1)	1	0.16
Occult blood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Liver function test increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	1	(0.1)	1	0.07
Blood cholesterol increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Arthroscopy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Blood glucose fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Heart rate increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Bone density decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Electrocardiogram abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Electrocardiogram ST segment abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Electrocardiogram T wave inversion								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hepatic enzyme increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Low density lipoprotein increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.27
Prostatic specific antigen increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Transaminases increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Catheterisation cardiac								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Eosinophil count increased								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.45
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Liver function test abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	2	0.27
Alanine aminotransferase increased								
<8% (<64 mmol/mol)	3	(0.3)	3	0.57	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Blood pressure increased								
<8% (<64 mmol/mol)	4	(0.4)	4	0.75	2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Blood triglycerides increased								
<8% (<64 mmol/mol)	3	(0.3)	3	0.53	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Glycosylated haemoglobin increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	2	0.15
Transferrin saturation decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Amylase increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Angiogram								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Antinuclear antibody positive								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Blood creatine increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Blood creatine phosphokinase increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Blood glucose decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Blood glucose increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.24
Blood potassium increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Blood pressure decreased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Blood testosterone decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Blood uric acid increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.16
Blood urine present								
<8% (<64 mmol/mol)	1	(0.1)	3	0.32	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Body temperature increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Breath sounds abnormal								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Carbohydrate antigen 19-9 increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Cardiac murmur								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Cardiac stress test abnormal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Ejection fraction decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Electrocardiogram P wave biphasic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram repolarisation abnormality								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram ST segment depression								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Free fatty acids increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Glomerular filtration rate decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Grip strength decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Haematocrit increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Haemoglobin increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatitis B virus test positive								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio increased								
<8% (<64 mmol/mol)	1	(0.1)	2	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Intraocular pressure increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Lipase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Lipids abnormal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Lipids increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Monocyte count decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Monofilament pressure perception test								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Mycobacterium tuberculosis complex test positive								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Occult blood positive								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Platelet count decreased								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
QRS axis abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Red blood cell count decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Thyroid function test abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Vitamin D decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
White blood cell count decreased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Vascular disorders								
All								
<8% (<64 mmol/mol)	30	(3.4)	34	5.28	23	(2.5)	25	3.50
>=8% (>=64 mmol/mol)	49	(3.8)	54	5.32	57	(4.5)	74	7.85
Hypertension								
<8% (<64 mmol/mol)	16	(1.8)	16	2.69	8	(0.9)	9	1.23
>=8% (>=64 mmol/mol)	21	(1.6)	21	2.13	30	(2.4)	34	3.74
Hypotension								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	2	(0.2)	2	0.16
Peripheral arterial occlusive disease								
<8% (<64 mmol/mol)	2	(0.2)	3	0.34	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	2	(0.2)	2	0.16
Arteriosclerosis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	6	(0.5)	6	0.64
Blood pressure inadequately controlled								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Superficial vein thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Peripheral artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	5	0.56	0			

%: Percentage of subjects with one or more events, E: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral coldness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Arterial insufficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Varicose ulceration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Hot flush								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Venous stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Deep vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Diabetic vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	2	(0.2)	2	0.27
Hypertensive crisis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	2	(0.2)	4	0.50
Flushing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Peripheral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Peripheral vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Peripheral venous disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.29
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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Aortic aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Aortic arteriosclerosis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.24	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.41
Aortic dilatation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Aortic stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Blood pressure fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Brachiocephalic arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Hypertensive urgency								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	3	0.29
Iliac artery stenosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Intermittent claudication								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Macroangiopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Neovascularisation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Orthostatic hypotension								
<8% (<64 mmol/mol)	2	(0.2)	2	0.38	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral artery aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Peripheral ischaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Phlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Thrombophlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	22	(2.5)	26	4.21	20	(2.2)	26	3.75
>=8% (>=64 mmol/mol)	32	(2.5)	39	3.92	34	(2.7)	44	4.24
Pollakiuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.48	1	(0.1)	1	0.08
Dysuria								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.44	2	(0.2)	2	0.22
Chronic kidney disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	5	(0.4)	5	0.45
Nephrolithiasis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	2	0.22
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	3	(0.2)	4	0.48
Renal impairment								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.29	2	(0.2)	2	0.16
Renal pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	0			
Acute kidney injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	3	(0.2)	3	0.23
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.24	1	(0.1)	1	0.07
Diabetic nephropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	3	(0.2)	3	0.42
Chromaturia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Renal failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Urethral stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Nocturia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Proteinuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Renal cyst								
<8% (<64 mmol/mol)	6	(0.7)	6	1.00	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	4	0.36
Ureterolithiasis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Urinary incontinence								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.22
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Urinary retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Haematuria								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.21
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.27	3	(0.2)	3	0.29
Calculus urinary								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Urine odour abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Bladder mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Bladder prolapse								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Cystitis haemorrhagic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Hydrocalyx								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	0				0			
Hydronephrosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Hypertensive nephropathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Hypertonic bladder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Micturition urgency								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Nephropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Nephrotic syndrome								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Polyuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Pyelocaliectasis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Renal colic								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.20

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.21
Renal mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Strangury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Stress urinary incontinence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Urinary tract disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Urinary tract inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Urinary tract obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	10	(1.1)	10	1.69	10	(1.1)	10	1.37
>=8% (>=64 mmol/mol)	26	(2.0)	28	2.94	23	(1.8)	23	2.42
Anaemia								
<8% (<64 mmol/mol)	5	(0.6)	5	0.76	5	(0.5)	5	0.62
>=8% (>=64 mmol/mol)	15	(1.2)	17	1.89	9	(0.7)	9	0.94
Eosinophilia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	1	(0.1)	1	0.14
Lymphadenopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.16
Lymphadenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Leukocytosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.22
Splenomegaly								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lymphadenopathy mediastinal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Iron deficiency anaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	4	0.45
Polycythaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Thrombocytopenia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Blood loss anaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hypochromic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Leukopenia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Normocytic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Pancytopenia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Thrombocytosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	13	(1.5)	15	2.13	11	(1.2)	15	2.15
>=8% (>=64 mmol/mol)	22	(1.7)	28	2.93	18	(1.4)	28	2.73
Eye naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	4	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Adenocarcinoma pancreas								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Metastases to liver								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Pancreatic neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Bladder papilloma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Lung cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.07
Skin papilloma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Haemangioma of liver								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Melanocytic naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Chronic myeloid leukaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Colon adenoma								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Bladder cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Invasive ductal breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Invasive lobular breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lipoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pancreatic carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Small cell lung cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Acrochordon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Neoplasm skin								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Oral fibroma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Salivary gland neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Seborrhoeic keratosis								
<8% (<64 mmol/mol)	1	(0.1)	2	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Adenocarcinoma of colon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Adrenal adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Basal cell carcinoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	3	(0.3)	3	0.32
>=8% (>=64 mmol/mol)	0				0			
Benign neoplasm of thyroid gland								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Benign renal neoplasm								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.34
>=8% (>=64 mmol/mol)	0				0			
Bowen's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Breast cancer								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Breast cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Colon cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Colon cancer stage II								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Colorectal cancer								
<8% (<64 mmol/mol)	2	(0.2)	2	0.29	0			
>=8% (>=64 mmol/mol)	0				0			
Dysplastic naevus								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Endometrial adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Gastric cancer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal tract adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Glioblastoma multiforme								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatocellular carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Invasive breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Lung adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Lymphangioma								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Malignant melanoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Malignant melanoma in situ								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Malignant peritoneal neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Metastases to bone marrow								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Metastases to lymph nodes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Myxoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Osteoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Pancreatic carcinoma metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Prostate cancer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Prostatic adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Renal cell carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Renal hamartoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07

%: 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Renal neoplasm								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Small intestine neuroendocrine tumour								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Squamous cell carcinoma of skin								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Uterine cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	0				3	(0.2)	3	0.29
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	11	(1.2)	11	1.81	10	(1.1)	14	2.36
>=8% (>=64 mmol/mol)	22	(1.7)	22	2.18	17	(1.3)	19	1.72
Erectile dysfunction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.44	1	(0.1)	1	0.13
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	2	(0.2)	2	0.34	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.42	2	(0.2)	2	0.16
Intermenstrual bleeding								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.27	0			
Breast pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Prostatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Prostatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Ejaculation failure								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Menstruation irregular								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pelvic discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Breast mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Ovarian cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Uterine polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Uterine prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Vulvovaginal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Atrophic vulvovaginitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Cervical polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Colpocele								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Dysmenorrhoea								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Ectropion of cervix								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Fibrocystic breast disease								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Galactorrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Genital prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Menopausal disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Menopausal symptoms								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Menstruation delayed								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Penile pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Penile rash								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.21
>=8% (>=64 mmol/mol)	0				0			
Premenstrual syndrome								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	0				0			
Prostatic calcification								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Pruritus genital								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.22
Testicular cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Uterine enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Vaginal discharge								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Vaginal haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.15
Vulvovaginal dryness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	20	(2.3)	20	3.17	13	(1.5)	16	2.84
>=8% (>=64 mmol/mol)	21	(1.6)	25	2.39	30	(2.4)	30	3.27
Insomnia								
<8% (<64 mmol/mol)	6	(0.7)	6	0.89	2	(0.2)	3	0.50
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.56	4	(0.3)	4	0.38
Depression								
<8% (<64 mmol/mol)	3	(0.3)	3	0.33	2	(0.2)	2	0.45
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.50	10	(0.8)	10	1.09
Anxiety								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	6	(0.7)	6	1.01
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	4	(0.3)	4	0.39
Sleep disorder								
<8% (<64 mmol/mol)	2	(0.2)	2	0.35	2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.23	2	(0.2)	2	0.27
Agitation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Drug abuse								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Irritability								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Listless								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post-traumatic stress disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Stress								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Depressed mood								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nightmare								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Adjustment disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Adjustment disorder with depressed mood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Adjustment disorder with mixed anxiety and depressed mood								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Affect lability								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Anxiety disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Attention deficit hyperactivity disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Bruxism								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Disorientation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Drug dependence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Emotional distress								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Fear								
<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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.28
Major depression								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Mental status changes								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Mixed anxiety and depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Mood swings								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Persistent depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Phobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	15	(1.7)	15	2.29	10	(1.1)	10	1.66
>=8% (>=64 mmol/mol)	13	(1.0)	16	1.40	14	(1.1)	15	1.53
Vertigo								
<8% (<64 mmol/mol)	6	(0.7)	6	0.84	3	(0.3)	3	0.44
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.50	6	(0.5)	7	0.74
Ear pain								
<8% (<64 mmol/mol)	4	(0.4)	4	0.71	1	(0.1)	1	0.23
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	1	(0.1)	1	0.13
Tinnitus								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.15	0			
Hypoacusis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	3	(0.2)	3	0.23
Deafness bilateral								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
External ear 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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Meniere's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Vertigo positional								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Ear inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eustachian tube dysfunction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cerumen impaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Deafness neurosensory								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Deafness unilateral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Ear discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Middle ear inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Motion sickness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Presbyacusis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	14	(1.6)	17	2.95	12	(1.3)	14	2.58
>=8% (>=64 mmol/mol)	10	(0.8)	14	1.31	13	(1.0)	15	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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatic steatosis								
<8% (<64 mmol/mol)	6	(0.7)	6	1.12	4	(0.4)	4	0.72
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.38	6	(0.5)	6	0.51
Hepatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.21	0			
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.30
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Gallbladder polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	3	(0.3)	3	0.65
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.13	0			
Cholelithiasis								
<8% (<64 mmol/mol)	2	(0.2)	2	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Cholecystitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Gallbladder cholesterolosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypertransaminasaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.15	0			
Alcoholic liver disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Bile duct stone								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.15
Biliary colic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	0				0			
Biliary dyskinesia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Cholecystitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Gallbladder disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Hepatic calcification								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatic cirrhosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hepatic cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hepatic mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.11	0			
>=8% (>=64 mmol/mol)	0				0			
Hyperplastic cholecystopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Liver disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Non-alcoholic steatohepatitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Nonalcoholic fatty liver disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Steatohepatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Immune system disorders								
All								
<8% (<64 mmol/mol)	7	(0.8)	8	1.27	7	(0.8)	8	1.32
>=8% (>=64 mmol/mol)	7	(0.5)	7	0.74	9	(0.7)	9	0.99
Seasonal allergy								
<8% (<64 mmol/mol)	4	(0.5)	4	0.54	4	(0.4)	4	0.72
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.36	5	(0.4)	5	0.52
Hypersensitivity								
<8% (<64 mmol/mol)	2	(0.2)	2	0.42	1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.16	0			
Food allergy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Drug hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Allergy to arthropod bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.27
Allergy to arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Anaphylactic reaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	0				0			
Immunisation reaction								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.21
>=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). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	2	(0.2)	2	0.31
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.49	3	(0.2)	3	0.23
Type V hyperlipidaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.20
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.35	0			
Corneal dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Atrial septal defect								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Congenital syphilitic osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cystic fibrosis lung								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	0			
>=8% (>=64 mmol/mol)	0				0			
Hydrocele								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	0			
>=8% (>=64 mmol/mol)	0				0			
Hypertrophic cardiomyopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				0			
Myotonic dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Endocrine disorders								
All								
<8% (<64 mmol/mol)	2	(0.2)	2	0.31	7	(0.8)	7	1.13
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.37	12	(0.9)	12	1.11
Autoimmune thyroiditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypothyroidism								
<8% (<64 mmol/mol)	1	(0.1)	1	0.19	2	(0.2)	2	0.42
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.2)	3	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypogonadism								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Thyroid mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.12	1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Adrenal mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Adrenocortical insufficiency acute								
<8% (<64 mmol/mol)	0				2	(0.2)	2	0.39
>=8% (>=64 mmol/mol)	0				0			
Goitre								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.11
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hyperplasia adrenal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hyperprolactinaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hyperthyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Inappropriate antidiuretic hormone secretion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Secondary hypogonadism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	2	(0.2)	2	0.46	1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.43	5	(0.4)	5	0.45
Cardiac pacemaker replacement								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.19
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Shoulder operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Tooth extraction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.14	0			
Knee operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cardiac ablation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				0			
Large intestinal polypectomy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Removal of foreign body								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Skin neoplasm excision								
<8% (<64 mmol/mol)	1	(0.1)	1	0.23	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Spinal operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.07
Toe amputation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Social circumstances								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13
Menopause								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.7.44 Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main- on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
<8% (<64 mmol/mol)	699				708			
>=8% (>=64 mmol/mol)	1181				1169			
Missing	0				1			
PYE (years)								
<8% (<64 mmol/mol)	557.73				565.93			
>=8% (>=64 mmol/mol)	981.19				970.20			
Missing	0.00				0.33			
Events								
<8% (<64 mmol/mol)	419	(60.1)	1294	246.05	404	(56.8)	1284	237.98
>=8% (>=64 mmol/mol)	720	(60.9)	2184	235.01	669	(57.3)	1975	213.92
Missing	0				0			
Infections and infestations								
All								
<8% (<64 mmol/mol)	186	(26.7)	254	48.83	199	(27.9)	287	52.67
>=8% (>=64 mmol/mol)	358	(30.3)	519	56.77	324	(27.8)	470	49.99
COVID-19								
<8% (<64 mmol/mol)	42	(6.0)	42	7.92	49	(6.9)	49	8.70
>=8% (>=64 mmol/mol)	110	(9.3)	113	12.06	111	(9.5)	116	11.64
Nasopharyngitis								
<8% (<64 mmol/mol)	31	(4.5)	36	7.06	29	(4.1)	35	7.08
>=8% (>=64 mmol/mol)	52	(4.4)	63	7.09	50	(4.3)	57	6.19
Upper respiratory tract infection								
<8% (<64 mmol/mol)	24	(3.5)	29	5.31	16	(2.2)	19	3.27
>=8% (>=64 mmol/mol)	38	(3.2)	46	4.78	29	(2.5)	29	3.20
Urinary tract infection								
<8% (<64 mmol/mol)	11	(1.6)	11	2.05	16	(2.2)	19	3.04
>=8% (>=64 mmol/mol)	26	(2.2)	29	3.37	28	(2.4)	29	3.08
Influenza								
<8% (<64 mmol/mol)	8	(1.1)	10	2.41	10	(1.4)	12	2.84
>=8% (>=64 mmol/mol)	20	(1.7)	21	2.72	18	(1.5)	19	2.41
Gastroenteritis								
<8% (<64 mmol/mol)	9	(1.3)	9	1.98	7	(1.0)	8	1.64
>=8% (>=64 mmol/mol)	17	(1.4)	17	2.13	9	(0.8)	9	1.14
Bronchitis								
<8% (<64 mmol/mol)	12	(1.7)	12	2.40	10	(1.4)	10	1.92
>=8% (>=64 mmol/mol)	14	(1.2)	15	1.64	7	(0.6)	7	0.70

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sinusitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	10	(1.4)	10	2.03
>=8% (>=64 mmol/mol)	12	(1.0)	14	1.49	7	(0.6)	10	0.92
COVID-19 pneumonia								
<8% (<64 mmol/mol)	4	(0.6)	4	0.67	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	10	(0.8)	10	1.15	7	(0.6)	7	0.71
Pharyngitis								
<8% (<64 mmol/mol)	7	(1.0)	8	1.19	7	(1.0)	8	1.43
>=8% (>=64 mmol/mol)	9	(0.8)	10	1.10	10	(0.9)	12	1.37
Tooth infection								
<8% (<64 mmol/mol)	0				6	(0.9)	6	1.26
>=8% (>=64 mmol/mol)	8	(0.7)	10	1.09	2	(0.2)	2	0.29
Cystitis								
<8% (<64 mmol/mol)	5	(0.7)	5	0.92	10	(1.4)	11	1.83
>=8% (>=64 mmol/mol)	7	(0.6)	8	0.92	6	(0.5)	7	0.85
Tooth abscess								
<8% (<64 mmol/mol)	0				5	(0.7)	6	1.14
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.84	2	(0.2)	2	0.16
Pneumonia								
<8% (<64 mmol/mol)	8	(1.2)	8	1.56	4	(0.6)	4	0.77
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.69	2	(0.2)	2	0.23
Herpes zoster								
<8% (<64 mmol/mol)	4	(0.6)	4	0.70	4	(0.6)	4	0.66
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.56	11	(0.9)	12	1.20
Rhinitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.57	7	(0.6)	9	1.08
Otitis media								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.61	3	(0.3)	3	0.38
Respiratory tract infection								
<8% (<64 mmol/mol)	3	(0.4)	3	0.55	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.55	3	(0.3)	3	0.39
Viral infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	7	(0.6)	10	0.84
Lower respiratory tract infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.42	2	(0.2)	4	0.36

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acute sinusitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	1	(0.1)	1	0.08
Respiratory tract infection viral								
<8% (<64 mmol/mol)	5	(0.7)	5	1.14	4	(0.6)	4	0.77
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.61	4	(0.3)	5	0.75
Conjunctivitis								
<8% (<64 mmol/mol)	4	(0.6)	4	0.77	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.33	4	(0.3)	4	0.46
Gastroenteritis viral								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	4	(0.3)	4	0.40
Fungal infection								
<8% (<64 mmol/mol)	4	(0.6)	5	0.91	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	1	(0.1)	1	0.09
Vaginal infection								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	1	(0.1)	1	0.15
Wound infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	0			
Ear infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	2	(0.2)	2	0.16
Cellulitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	5	(0.4)	6	0.76
Coronavirus infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	4	0.55
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	1	(0.1)	2	0.30
Vulvovaginal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	4	0.40	4	(0.4)	4	0.36
Laryngitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	3	(0.3)	3	0.38
Gastrointestinal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	3	(0.3)	4	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Otitis externa								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.17
Helicobacter infection								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Oral herpes								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.44	0			
Sepsis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	0			
Acarodermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	3	(0.3)	3	0.25
Furuncle								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.32	2	(0.2)	2	0.17
Osteomyelitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Candida infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.25	4	(0.3)	4	0.53
Hordeolum								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.64
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Erysipelas								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	3	0.37
Genital candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Genital infection								
<8% (<64 mmol/mol)	2	(0.3)	2	0.27	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injection site abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Oral candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Postoperative wound infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Abscess limb								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Anal abscess								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Fungal skin infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Kidney infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Paraspinal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Pulpitis dental								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	3	(0.3)	3	0.38
Pustule								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Vulvitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Appendicitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Chronic sinusitis								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Clostridium difficile colitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Ear infection fungal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Gangrene								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nail infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	1	(0.1)	1	0.09
Paronychia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	2	0.30
Post-acute COVID-19 syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	0			
Pyelonephritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Subcutaneous abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	3	0.26
Tinea cruris								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tonsillitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Viral pharyngitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diabetic foot infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Periodontitis								
<8% (<64 mmol/mol)	3	(0.4)	3	0.55	5	(0.7)	5	0.91
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pneumonia viral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Pulmonary tuberculoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Balanitis candida								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Chlamydial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Chronic tonsillitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Dermatophytosis of nail								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Genital infection fungal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Herpes simplex								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Herpes virus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Infected bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Localised infection								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Mastitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Onychomycosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Oropharyngeal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Otitis media chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tinea infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Urethritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Viral upper respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.18
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Abdominal abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Bacteraemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Bacterial infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Bartholinitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Body tinea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Breast abscess								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.18
Breast cellulitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Campylobacter gastroenteritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Cholecystitis infective								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Chronic hepatitis C								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Clostridium difficile infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Diverticulitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.35
Empyema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Endophthalmitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Enteritis infectious								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Epididymitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Escherichia bacteraemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Escherichia urinary tract infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eye infection								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Eye infection bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Folliculitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Fungal balanitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Gastroenteritis norovirus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Giardiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Helicobacter gastritis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Herpes dermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Herpes zoster infection neurological								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Infected dermal cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Infective iritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Labyrinthitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Laryngopharyngitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Lyme disease								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Oophoritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Otitis media acute								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Parotitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Peri-implantitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Pericoronitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Peritonsillar abscess								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Pharyngotonsillitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Post procedural infection								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Purulence								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory syncytial virus infection								
<8% (<64 mmol/mol)	3	(0.4)	3	0.53	0			
>=8% (>=64 mmol/mol)	0				0			
Rotavirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Salpingitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sinusitis bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Skin bacterial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Skin candida								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Skin infection								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Soft tissue infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.30
Suspected COVID-19								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Sweat gland infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Tinea pedis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Tinea versicolour								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Tracheitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Urosepsis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Varicella								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Varicella zoster virus infection								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Viral rhinitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Viral tracheitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	106	(15.2)	142	26.96	87	(12.2)	116	20.80
>=8% (>=64 mmol/mol)	145	(12.2)	238	25.01	134	(11.5)	186	21.12
Diarrhoea								
<8% (<64 mmol/mol)	41	(5.9)	44	8.06	21	(2.9)	22	3.88
>=8% (>=64 mmol/mol)	43	(3.6)	58	6.43	30	(2.6)	30	3.63
Nausea								
<8% (<64 mmol/mol)	15	(2.2)	16	3.01	8	(1.1)	8	1.43
>=8% (>=64 mmol/mol)	22	(1.9)	22	2.28	19	(1.6)	21	2.34
Vomiting								
<8% (<64 mmol/mol)	10	(1.4)	10	2.24	7	(1.0)	7	1.17
>=8% (>=64 mmol/mol)	14	(1.2)	22	2.60	9	(0.8)	12	1.29
Abdominal pain								
<8% (<64 mmol/mol)	4	(0.6)	4	0.88	6	(0.8)	7	1.29
>=8% (>=64 mmol/mol)	12	(1.0)	12	1.19	12	(1.0)	12	1.40
Constipation								
<8% (<64 mmol/mol)	6	(0.9)	7	1.48	6	(0.8)	6	1.15
>=8% (>=64 mmol/mol)	10	(0.8)	12	1.32	10	(0.9)	10	1.22
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	3	(0.4)	3	0.63	7	(1.0)	7	1.17
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.96	7	(0.6)	7	0.84
Toothache								
<8% (<64 mmol/mol)	4	(0.6)	4	0.68	4	(0.6)	5	1.23
>=8% (>=64 mmol/mol)	9	(0.7)	9	0.81	6	(0.5)	8	1.06
Abdominal pain upper								
<8% (<64 mmol/mol)	6	(0.8)	8	1.60	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.65	12	(1.0)	13	1.35
Dental caries								
<8% (<64 mmol/mol)	4	(0.6)	5	0.76	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	7	(0.6)	8	0.67	7	(0.6)	7	0.90
Chronic gastritis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.78	3	(0.3)	3	0.33
Abdominal distension								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.65	2	(0.2)	2	0.30
Haemorrhoids								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	1	(0.1)	1	0.15
Food poisoning								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	4	(0.6)	5	1.12
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	0			
Gastritis								
<8% (<64 mmol/mol)	4	(0.6)	4	0.75	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	6	(0.5)	6	0.61
Dyspepsia								
<8% (<64 mmol/mol)	4	(0.6)	4	0.66	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.44	6	(0.5)	6	0.63
Large intestine polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	4	0.66
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	3	(0.3)	3	0.25
Hiatus hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.09
Diverticulum intestinal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.08
Hypoaesthesia oral								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	2	(0.2)	4	0.53	0			
Flatulence								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.14
Abdominal pain lower								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Rectal polyp								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.08
Abdominal discomfort								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	4	0.87
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.17

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Noninfective gingivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Oral pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Vomiting projectile								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Diverticulum								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	2	0.23
Gastrointestinal angiodysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Gingival bleeding								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Anal fissure								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Aphthous ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis microscopic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Diabetic gastropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eructation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Gastric ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Impaired gastric emptying								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Intestinal dilatation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Umbilical hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.18
Pancreatitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.09
Anal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Colitis ischaemic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Enterocolitis								
<8% (<64 mmol/mol)	2	(0.3)	3	0.45	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Frequent bowel movements								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Haematochezia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hyperaesthesia teeth								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Loose tooth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Oral discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pancreatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.30
Tooth disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tooth impacted								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Abdominal wall disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Acid peptic disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.18
Crohn's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Dry mouth								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Duodenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Enteritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Eosinophilic oesophagitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Epigastric discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Faeces pale								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Gastric dilatation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Gastric disorder								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Gastric dysplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Gastric mucosal hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Gastric polyps								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Gastrointestinal disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal sounds abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Gingival disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Haemorrhoidal haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Hyperchlorhydria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Ileus								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	0				0			
Inguinal hernia								
<8% (<64 mmol/mol)	2	(0.3)	2	0.27	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.18
Intra-abdominal haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Irritable bowel syndrome								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Lip swelling								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Melaena								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Mesenteric panniculitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Odynophagia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Oesophageal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Oesophagitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Pancreatic duct dilatation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatic failure								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Pancreatic pseudocyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Pancreatitis acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Peptic ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Periodontal inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	0				0			
Proctalgia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Rectal prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Small intestinal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Stomatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Tongue rough								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Ulcerative gastritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Upper gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	104	(15.0)	163	30.44	87	(12.2)	123	22.87
>=8% (>=64 mmol/mol)	142	(12.0)	206	21.69	158	(13.6)	215	23.39
Back pain								
<8% (<64 mmol/mol)	28	(4.1)	30	5.88	21	(2.9)	23	4.56
>=8% (>=64 mmol/mol)	34	(2.9)	36	3.71	40	(3.4)	41	4.64
Pain in extremity								
<8% (<64 mmol/mol)	8	(1.2)	8	1.34	16	(2.3)	19	4.04
>=8% (>=64 mmol/mol)	23	(1.9)	25	2.40	15	(1.3)	18	1.94
Arthralgia								
<8% (<64 mmol/mol)	24	(3.5)	30	5.49	22	(3.1)	24	4.50
>=8% (>=64 mmol/mol)	21	(1.8)	23	2.49	26	(2.2)	30	3.45
Muscle spasms								
<8% (<64 mmol/mol)	9	(1.3)	9	1.86	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	14	(1.2)	16	1.84	6	(0.5)	6	0.64
Osteoarthritis								
<8% (<64 mmol/mol)	9	(1.3)	10	1.98	7	(1.0)	10	1.91
>=8% (>=64 mmol/mol)	12	(1.0)	13	1.22	17	(1.5)	17	1.77
Myalgia								
<8% (<64 mmol/mol)	7	(1.0)	7	1.31	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.90	6	(0.5)	6	0.76

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Neck pain								
<8% (<64 mmol/mol)	8	(1.1)	8	1.74	5	(0.7)	5	0.90
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.65	3	(0.3)	3	0.27
Tendonitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	6	(0.5)	8	0.85	2	(0.2)	2	0.24
Periarthritis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.56	4	(0.3)	4	0.41
Trigger finger								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.67	5	(0.4)	7	0.67
Arthritis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.39	3	(0.3)	3	0.38
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	0			
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	4	(0.6)	8	1.24	1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	5	(0.4)	5	0.55
Exostosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	1	(0.1)	1	0.09
Intervertebral disc disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	1	(0.1)	1	0.14
Plantar fasciitis								
<8% (<64 mmol/mol)	1	(0.1)	2	0.30	0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	3	(0.3)	3	0.25
Rotator cuff syndrome								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.32	3	(0.3)	3	0.24
Muscular weakness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	3	(0.3)	3	0.38
Osteoporosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	0			
Bursitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.18
Musculoskeletal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Musculoskeletal chest pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.08
Back disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Fibromyalgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Groin pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Pain in jaw								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Tendon disorder								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Torticollis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Polymyalgia rheumatica								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	3	0.44
Soft tissue swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	3	0.44	0			
Diastasis recti abdominis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Facet joint syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Foot deformity								
<8% (<64 mmol/mol)	2	(0.3)	3	0.52	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	2	(0.2)	2	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Joint effusion								
<8% (<64 mmol/mol)	1	(0.1)	2	0.48	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Psoriatic arthropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal osteoarthritis								
<8% (<64 mmol/mol)	5	(0.7)	5	0.93	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	5	0.41
Osteochondrosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	4	(0.3)	4	0.47
Costochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Polyarthritis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.32
Spinal stenosis								
<8% (<64 mmol/mol)	3	(0.4)	5	1.10	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Synovial cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Acquired claw toe								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Arthropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Axillary mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Bone cyst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Bone pain								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Cervical spinal stenosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Chondropathy								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	0			
>=8% (>=64 mmol/mol)	0				0			
Coccydynia								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Dupuytren's contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.18
Fistula								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Flank pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				5	(0.4)	6	0.63
Haemarthrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Intervertebral disc degeneration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Intervertebral disc space narrowing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16
Jaw disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Joint swelling								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.50
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Limb deformity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Lumbar spinal stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mastication disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.18
Meniscopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Muscle contracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Muscle twitching								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Myositis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Neuropathic arthropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Nodal osteoarthritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Osteopenia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Periostitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Rheumatoid arthritis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Sacroiliitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Scoliosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Spinal retrolisthesis								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16
Tenosynovitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	4	0.55
>=8% (>=64 mmol/mol)	0				6	(0.5)	6	0.64
Tenosynovitis stenosans								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Vertebral osteophyte								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	72	(10.4)	109	21.49	89	(12.4)	135	24.05
>=8% (>=64 mmol/mol)	127	(10.7)	204	23.38	85	(7.3)	126	13.00
Fatigue								
<8% (<64 mmol/mol)	7	(1.0)	9	1.69	8	(1.1)	8	1.10
>=8% (>=64 mmol/mol)	20	(1.7)	21	2.20	7	(0.6)	7	0.84
Pyrexia								
<8% (<64 mmol/mol)	13	(1.9)	13	2.66	17	(2.4)	17	3.08
>=8% (>=64 mmol/mol)	19	(1.6)	20	1.93	20	(1.7)	22	2.42
Oedema peripheral								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	4	(0.6)	4	0.76
>=8% (>=64 mmol/mol)	15	(1.3)	15	1.76	5	(0.4)	6	0.53
Chest pain								
<8% (<64 mmol/mol)	3	(0.4)	3	0.42	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	11	(0.9)	11	1.24	3	(0.3)	3	0.25
Injection site reaction								
<8% (<64 mmol/mol)	6	(0.8)	15	3.49	4	(0.6)	6	1.16
>=8% (>=64 mmol/mol)	9	(0.8)	14	2.00	2	(0.2)	2	0.17
Malaise								
<8% (<64 mmol/mol)	5	(0.7)	6	0.99	7	(1.0)	10	1.69
>=8% (>=64 mmol/mol)	8	(0.7)	9	0.94	5	(0.4)	6	0.66
Asthenia								
<8% (<64 mmol/mol)	3	(0.4)	3	0.64	8	(1.1)	8	1.42
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.78	0			
Pain								
<8% (<64 mmol/mol)	3	(0.4)	4	0.98	6	(0.8)	6	1.04
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.78	8	(0.7)	9	1.01

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vaccination site pain								
<8% (<64 mmol/mol)	4	(0.6)	5	1.02	4	(0.5)	4	0.65
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.84	4	(0.3)	4	0.59
Chest discomfort								
<8% (<64 mmol/mol)	3	(0.4)	3	0.52	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.61	0			
Peripheral swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	5	(0.4)	6	0.63	3	(0.3)	3	0.38
Medical device site bruise								
<8% (<64 mmol/mol)	1	(0.1)	2	0.48	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.42	0			
Injection site pain								
<8% (<64 mmol/mol)	0				6	(0.9)	6	1.27
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.44	6	(0.5)	24	2.15
Influenza like illness								
<8% (<64 mmol/mol)	1	(0.1)	2	0.27	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.44	2	(0.2)	2	0.17
Injection site pruritus								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	3	(0.3)	18	2.60	0			
Medical device site reaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	5	0.55	0			
Chills								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	0			
Drug intolerance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	0			
Injection site bruising								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.17
Injection site haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.23
Injection site erythema								
<8% (<64 mmol/mol)	1	(0.1)	3	0.72	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.09
Medical device site dermatitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	5	(0.7)	11	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	2	(0.2)	5	0.48	3	(0.3)	3	0.27
Thirst								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.14
Gait disturbance								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.08
Injection site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Medical device site pruritus								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Application site bruise								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Application site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Discomfort								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	8	1.96
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	2	0.17
Injection site haematoma								
<8% (<64 mmol/mol)	1	(0.1)	4	0.96	1	(0.1)	5	1.24
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.30	2	(0.2)	3	0.43
Injection site swelling								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
Medical device site erythema								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Early satiety								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injection site mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Localised oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Multiple organ dysfunction syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Oedema								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Vaccination site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Vaccination site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Feeling hot								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Implant site pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injection site dermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site eczema								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site haemorrhage								
<8% (<64 mmol/mol)	3	(0.4)	3	0.45	2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Medical device site pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Axillary pain								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Condition aggravated								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Cyst								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Death								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.25
Facial pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Feeling abnormal								
<8% (<64 mmol/mol)	3	(0.4)	5	0.95	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Hernia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Hunger								
<8% (<64 mmol/mol)	6	(0.9)	7	1.15	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	0				0			
Injection site hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Injection site induration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Injection site oedema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Injection site rash								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Injection site urticaria								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Medical device site haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Medical device site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Medical device site rash								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Non-cardiac chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				4	(0.3)	6	0.50
Oedema due to renal disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Procedural failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Swelling face								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Systemic inflammatory response syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vaccination site erythema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Vaccination site reaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Vessel puncture site bruise								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Xerosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Nervous system disorders								
All								
<8% (<64 mmol/mol)	73	(10.5)	107	20.67	73	(10.2)	112	21.76
>=8% (>=64 mmol/mol)	107	(9.0)	145	15.80	110	(9.4)	136	14.92
Headache								
<8% (<64 mmol/mol)	22	(3.2)	28	5.48	26	(3.6)	37	6.59
>=8% (>=64 mmol/mol)	35	(3.0)	45	5.47	28	(2.4)	30	3.53

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dizziness								
<8% (<64 mmol/mol)	20	(2.9)	28	5.80	13	(1.8)	16	3.50
>=8% (>=64 mmol/mol)	18	(1.5)	20	1.86	24	(2.1)	28	3.08
Sciatica								
<8% (<64 mmol/mol)	4	(0.6)	4	0.85	5	(0.7)	5	0.90
>=8% (>=64 mmol/mol)	9	(0.8)	9	1.01	7	(0.6)	8	0.81
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	3	(0.4)	3	0.63	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	8	(0.7)	8	0.79	6	(0.5)	6	0.71
Paraesthesia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	7	(1.0)	7	1.40
>=8% (>=64 mmol/mol)	7	(0.6)	8	0.73	5	(0.4)	5	0.60
Hypoaesthesia								
<8% (<64 mmol/mol)	4	(0.6)	7	1.32	5	(0.7)	5	1.01
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.55	4	(0.3)	5	0.49
Syncope								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	1	(0.1)	1	0.09
Migraine								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	2	(0.2)	2	0.24
Diabetic neuropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	9	(0.8)	9	1.01
Neuropathy peripheral								
<8% (<64 mmol/mol)	3	(0.4)	3	0.64	5	(0.7)	5	0.91
>=8% (>=64 mmol/mol)	3	(0.3)	4	0.46	4	(0.3)	4	0.40
Tremor								
<8% (<64 mmol/mol)	8	(1.2)	9	1.49	3	(0.4)	7	1.72
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	5	(0.4)	5	0.61
Amnesia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Neuralgia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Dysgeusia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Vascular headache								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Carotid artery aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Cervicobrachial syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Peripheral paralysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Piriformis syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Thalamic infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Carotid artery stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Disturbance in attention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Intracranial pressure increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cerebral arteriosclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Cerebrovascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Memory impairment								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Vascular encephalopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Ageusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Anosmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Balance disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Burning sensation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Dizziness postural								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lumbar radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	5	0.43
Neuroglycopenia								
<8% (<64 mmol/mol)	0				1	(0.1)	3	0.41
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Tension headache								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	0			
Trigeminal neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Autonomic nervous system imbalance								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Basilar migraine								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Brain injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Carotid arteriosclerosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Cerebral artery embolism								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cerebral atrophy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Cerebral haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Cerebral infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Cerebrovascular accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Cervical radiculopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Cluster headache								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Cognitive disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Dementia Alzheimer's type								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Essential tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Facial nerve disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Facial paralysis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Hemiparesis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic coma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyporeflexia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Ischaemic stroke								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Lethargy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.18
Loss of consciousness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Mental impairment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Meralgia paraesthetica								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Morton's neuralgia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Myelopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Ophthalmic migraine								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Orthostatic tremor								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Parkinsonian gait								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Presyncope								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.34
Radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Restless legs syndrome								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Sleep deficit								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Somnolence								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Thrombotic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Transient ischaemic attack								
<8% (<64 mmol/mol)	3	(0.4)	3	0.53	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	0				0			
Vertebral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
White matter lesion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Eye disorders								
All								
<8% (<64 mmol/mol)	46	(6.6)	62	12.49	63	(8.9)	90	18.45
>=8% (>=64 mmol/mol)	101	(8.6)	126	14.33	89	(7.6)	109	12.69
Diabetic retinopathy								
<8% (<64 mmol/mol)	16	(2.3)	17	3.73	22	(3.1)	22	4.75
>=8% (>=64 mmol/mol)	36	(3.1)	41	5.20	36	(3.1)	40	4.77
Cataract								
<8% (<64 mmol/mol)	3	(0.4)	4	0.66	11	(1.6)	12	1.88
>=8% (>=64 mmol/mol)	21	(1.8)	25	2.53	14	(1.2)	16	1.92
Macular oedema								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.90	3	(0.3)	3	0.24
Dry eye								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.56	3	(0.3)	3	0.32
Vision blurred								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	4	(0.3)	4	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Blepharitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.32	0			
Eye pain								
<8% (<64 mmol/mol)	2	(0.3)	2	0.27	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	3	(0.3)	3	0.33
Retinopathy hypertensive								
<8% (<64 mmol/mol)	4	(0.6)	4	0.87	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.31	4	(0.3)	4	0.53
Diabetic retinal oedema								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	7	(0.6)	8	0.99
Retinal haemorrhage								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Conjunctivitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.32	0			
Ocular hyperaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	2	0.50
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.30	0			
Cataract nuclear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Epiretinal membrane								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Lacrimation increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
Retinal exudates								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Retinal vein occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.09
Age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Amaurosis fugax								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Arteriosclerotic retinopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Conjunctival suffusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Glaucoma								
<8% (<64 mmol/mol)	2	(0.3)	2	0.27	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Maculopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Retinal degeneration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Visual impairment								
<8% (<64 mmol/mol)	0				2	(0.3)	10	2.34
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Presbyopia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Retinal deposits								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Asthenopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Astigmatism								
<8% (<64 mmol/mol)	1	(0.1)	2	0.27	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Conjunctival erosion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diplopia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eye inflammation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Posterior capsule opacification								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Retinal tear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Acquired epiblepharon								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Angle closure glaucoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Chorioretinal atrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Conjunctival hyperaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Corneal bleeding								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Corneal erosion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Cystoid macular oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Dacryoadenitis acquired								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Dry age-related macular degeneration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Eye discharge								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Eye irritation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Eye pruritus								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.50
>=8% (>=64 mmol/mol)	0				0			
Eyelid oedema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Hypermetropia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Macular degeneration								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Macular hole								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Meibomianitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Myopia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	1	(0.1)	2	0.48	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Normal tension glaucoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Ocular hypertension								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Ocular ischaemic syndrome								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Open angle glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ophthalmic vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Optic disc haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Optic disc vascular disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Photophobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Post thrombotic retinopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal aneurysm								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Retinal artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.17
Retinal detachment								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Retinal drusen								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Retinal scar								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal vascular disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Retinopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Scintillating scotoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Uveitis								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Visual acuity reduced								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Vitreous degeneration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Vitreous floaters								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Vitreous haemorrhage								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Vitreous opacities								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	66	(9.5)	87	16.60	58	(8.2)	70	13.63
>=8% (>=64 mmol/mol)	98	(8.3)	117	12.63	89	(7.6)	108	12.35
Fall								
<8% (<64 mmol/mol)	9	(1.3)	9	1.67	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.96	7	(0.6)	8	0.79
Contusion								
<8% (<64 mmol/mol)	5	(0.7)	6	1.18	4	(0.5)	4	0.55
>=8% (>=64 mmol/mol)	9	(0.8)	9	0.88	3	(0.3)	3	0.32
Vaccination complication								
<8% (<64 mmol/mol)	8	(1.2)	12	2.51	10	(1.4)	11	1.83
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.65	11	(0.9)	16	1.72
Ligament sprain								
<8% (<64 mmol/mol)	3	(0.4)	3	0.54	4	(0.6)	4	0.88
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.75	4	(0.3)	4	0.46
Skin abrasion								
<8% (<64 mmol/mol)	3	(0.4)	5	0.71	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.67	3	(0.3)	3	0.38
Road traffic accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Limb injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	3	(0.3)	4	0.59
Upper limb fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	0			
Procedural pain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	0			
Thermal burn								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	1	(0.1)	1	0.15
Incorrect dose administered								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.45	4	(0.3)	6	0.81
Accidental overdose								
<8% (<64 mmol/mol)	4	(0.6)	4	0.85	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	2	(0.2)	3	0.44
Joint injury								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.32	4	(0.3)	4	0.40
Medication error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.29
Hand fracture								
<8% (<64 mmol/mol)	4	(0.6)	4	0.68	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.08
Rib fracture								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	4	(0.3)	4	0.40
Tendon rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.15
Arthropod bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	2	(0.2)	2	0.23
Foot fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Radius fracture								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Skin laceration								
<8% (<64 mmol/mol)	5	(0.7)	5	1.02	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Tooth fracture								
<8% (<64 mmol/mol)	2	(0.3)	2	0.49	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Fibula fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Wound								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	3	(0.3)	3	0.38
Gun shot wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Ligament rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.30	0			
Procedural complication								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Facial bones fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.09
Ankle fracture								
<8% (<64 mmol/mol)	3	(0.4)	3	0.42	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Arthropod sting								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Back injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Bone contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hip fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Inflammation of wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Injury of conjunctiva								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Neck injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Penile contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post procedural inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Radiation skin injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Spinal compression fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Accidental underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Extra dose administered								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Wrong product administered								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.30	0			
Burn oral cavity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Burns first degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cervical vertebral fracture								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eye injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Heat illness								
<8% (<64 mmol/mol)	0				2	(0.3)	3	0.52
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Meniscus injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Overdose								
<8% (<64 mmol/mol)	3	(0.4)	3	0.72	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.38
Post procedural fistula								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post procedural hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Scar								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Animal bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.32
Chillblains								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Concussion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Craniocerebral injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Crush injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Deafness traumatic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Endotracheal intubation complication								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Epicondylitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Exposure to SARS-CoV-2								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Face injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Femoral neck fracture								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Head injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Humerus fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Injury								
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	0			
>=8% (>=64 mmol/mol)	0				0			
Intentional overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Intentional product use issue								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Lower limb fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Multiple injuries								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Muscle contusion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Muscle injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.30
Muscle strain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.24
Periprocedural myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Post procedural complication								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural haematuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural haemorrhage								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Post procedural swelling								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	0				0			
Post-traumatic neck syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Product administration error								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Scratch								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Seroma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Soft tissue injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Spinal column injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Stab wound								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Subcutaneous haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Subdural haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Sunburn								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Tendon injury								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Tibia fracture								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Traumatic haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Underdose								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.38
Wrong dose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	42	(6.0)	53	9.76	50	(7.0)	58	11.13
>=8% (>=64 mmol/mol)	82	(6.9)	100	10.20	75	(6.4)	100	10.62
Dyslipidaemia								
<8% (<64 mmol/mol)	8	(1.2)	8	1.38	7	(1.0)	7	1.51
>=8% (>=64 mmol/mol)	13	(1.1)	14	1.69	10	(0.9)	10	1.23
Vitamin D deficiency								
<8% (<64 mmol/mol)	4	(0.6)	4	0.57	6	(0.8)	6	1.04
>=8% (>=64 mmol/mol)	12	(1.0)	12	1.06	6	(0.5)	6	0.50
Hypertriglyceridaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	9	(0.8)	9	0.88	6	(0.5)	6	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypoglycaemia								
<8% (<64 mmol/mol)	5	(0.7)	9	1.99	9	(1.3)	10	2.03
>=8% (>=64 mmol/mol)	8	(0.7)	10	1.22	11	(1.0)	26	2.77
Vitamin B12 deficiency								
<8% (<64 mmol/mol)	4	(0.6)	4	0.54	0			
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.58	1	(0.1)	1	0.08
Hyperlipidaemia								
<8% (<64 mmol/mol)	8	(1.1)	8	1.44	5	(0.7)	5	0.91
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.63	8	(0.7)	8	0.80
Hyperkalaemia								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	5	(0.7)	5	1.12
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.71	5	(0.4)	5	0.49
Gout								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.42	5	(0.4)	6	0.50
Hyperglycaemia								
<8% (<64 mmol/mol)	3	(0.4)	3	0.61	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	3	(0.3)	4	0.53	11	(0.9)	11	1.34
Iron deficiency								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	3	(0.3)	3	0.24
Decreased appetite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	5	(0.7)	5	0.80
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.25	0			
Hyperuricaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.16
Folate deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.08
Hypercholesterolaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	2	(0.2)	2	0.30
Hypokalaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.09
Dehydration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Diabetes mellitus								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Diabetes mellitus inadequate control								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypernatraemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Magnesium deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Malnutrition								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Vitamin B complex deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypoalbuminaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Hyponatraemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Fluid retention								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Increased appetite								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	3	(0.4)	4	0.88
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.38
Obesity								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Abnormal weight gain								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Appetite disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	0				0			
Electrolyte imbalance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Food craving								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Hyperammonaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Hypercalcaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Insulin resistance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lactic acidosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lipomatosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Metabolic acidosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Metabolic disorder								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Zinc deficiency								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	42	(6.1)	55	10.70	41	(5.7)	55	9.94
>=8% (>=64 mmol/mol)	69	(5.8)	96	10.35	60	(5.1)	69	7.65
Cough								
<8% (<64 mmol/mol)	7	(1.0)	7	1.50	7	(1.0)	8	1.43
>=8% (>=64 mmol/mol)	16	(1.3)	17	1.67	13	(1.1)	13	1.37
Oropharyngeal pain								
<8% (<64 mmol/mol)	9	(1.3)	10	1.77	5	(0.7)	5	0.91
>=8% (>=64 mmol/mol)	10	(0.8)	11	1.05	11	(0.9)	13	1.55
Nasal congestion								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	8	(0.7)	8	0.79	2	(0.2)	2	0.17
Dyspnoea								
<8% (<64 mmol/mol)	2	(0.3)	2	0.49	5	(0.7)	6	1.25
>=8% (>=64 mmol/mol)	7	(0.6)	7	0.77	8	(0.7)	8	0.81
Rhinorrhoea								
<8% (<64 mmol/mol)	4	(0.6)	6	1.25	4	(0.6)	4	0.66
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.77	3	(0.3)	3	0.32
Epistaxis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	2	0.49
>=8% (>=64 mmol/mol)	4	(0.3)	8	1.17	1	(0.1)	2	0.18
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	3	(0.4)	3	0.54	0			
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	0			
Productive cough								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	1	(0.1)	1	0.15
Chronic obstructive pulmonary disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	0			
Sinus congestion								
<8% (<64 mmol/mol)	2	(0.3)	3	0.54	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Asthma								
<8% (<64 mmol/mol)	3	(0.4)	3	0.63	0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.32	1	(0.1)	1	0.15
Emphysema								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Pulmonary fibrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.32	0			
Bronchospasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
Nasal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Acute respiratory failure								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Increased viscosity of upper respiratory secretion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Rhinitis allergic								
<8% (<64 mmol/mol)	0				3	(0.4)	7	1.18
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.29
Upper respiratory tract inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Nasal septum deviation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Pleurisy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Pulmonary hypertension								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Respiratory disorder								
<8% (<64 mmol/mol)	3	(0.4)	3	0.64	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	2	0.30
Bronchiectasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Interstitial lung disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Laryngeal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nasal turbinate hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Sneezing								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Throat irritation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Acquired diaphragmatic eventration								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Acute pulmonary oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Allergic bronchitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Allergic cough								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Aphonia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Bronchitis chronic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Dry throat								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Dysphonia								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.50
>=8% (>=64 mmol/mol)	0				0			
Haemoptysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Lung disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Nasal dryness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Paranasal cyst								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	0				0			
Paranasal sinus 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Pleural disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Pleural effusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.25
Pleuritic pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Pulmonary embolism								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Pulmonary mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Respiratory failure								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Respiratory tract inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Sinus pain								
<8% (<64 mmol/mol)	2	(0.3)	3	0.55	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac disorders								
All								
<8% (<64 mmol/mol)	30	(4.3)	44	7.50	34	(4.8)	48	8.23
>=8% (>=64 mmol/mol)	56	(4.7)	80	7.69	45	(3.9)	61	6.15
Coronary artery disease								
<8% (<64 mmol/mol)	2	(0.3)	2	0.38	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	10	(0.8)	10	0.90	8	(0.7)	8	0.80
Angina pectoris								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.56	1	(0.1)	1	0.09
Myocardial infarction								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.69	3	(0.3)	3	0.26
Atrial fibrillation								
<8% (<64 mmol/mol)	6	(0.9)	6	0.87	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	6	(0.5)	7	0.65	5	(0.4)	5	0.51
Acute myocardial infarction								
<8% (<64 mmol/mol)	4	(0.6)	4	0.88	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.42	6	(0.5)	6	0.64
Cardiac failure								
<8% (<64 mmol/mol)	3	(0.4)	3	0.42	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	1	(0.1)	2	0.30
Acute coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.33	0			
Palpitations								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	4	(0.6)	4	0.66
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.33	1	(0.1)	1	0.09
Tachycardia								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	4	(0.3)	4	0.39
Angina unstable								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.25	1	(0.1)	1	0.09
Ventricular extrasystoles								
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	1	(0.1)	2	0.28
>=8% (>=64 mmol/mol)	3	(0.2)	3	0.25	1	(0.1)	1	0.09
Supraventricular tachycardia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Myocardial ischaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.17
Cardiac failure congestive								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	3	0.73
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Cardio-respiratory arrest								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Mitral valve stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Supraventricular extrasystoles								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.09
Cardiac flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Arteriosclerosis coronary artery								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Atrioventricular block first degree								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mitral valve incompetence								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Aortic valve sclerosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Left atrial enlargement								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Atrial flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Atrial thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cardiac failure chronic								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Chronic coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Coronary artery occlusion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Left atrial dilatation								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pericarditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Tricuspid valve incompetence								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.16
Aortic valve calcification								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Aortic valve incompetence								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Arrhythmia								
<8% (<64 mmol/mol)	2	(0.3)	2	0.27	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Atrial enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Atrioventricular block complete								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Bradycardia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Bundle branch block left								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Bundle branch block right								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	2	(0.3)	3	0.41
>=8% (>=64 mmol/mol)	0				4	(0.3)	4	0.46
Cardiac arrest								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	0				0			
Cardiac dysfunction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Cardiac failure acute								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac perfusion defect								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.49
>=8% (>=64 mmol/mol)	0				0			
Cardiac ventricular thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Coronary artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Diastolic dysfunction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Left ventricular dysfunction								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Pericardial effusion								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Sinus arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Sinus bradycardia								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	0				0			
Sinus tachycardia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.25
Subendocardial ischaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Ventricular arrhythmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Ventricular tachycardia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	45	(6.5)	47	9.05	36	(5.0)	44	7.77

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	54	(4.5)	60	6.02	68	(5.8)	79	8.25
Rash								
<8% (<64 mmol/mol)	3	(0.4)	3	0.52	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	8	(0.7)	8	0.92	10	(0.9)	11	1.07
Pruritus								
<8% (<64 mmol/mol)	3	(0.4)	3	0.61	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	8	(0.7)	8	0.87
Eczema								
<8% (<64 mmol/mol)	5	(0.7)	5	0.92	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	3	(0.3)	3	0.38
Urticaria								
<8% (<64 mmol/mol)	3	(0.4)	3	0.61	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	6	(0.5)	6	0.57
Dermatitis contact								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.42	6	(0.5)	6	0.59
Skin ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.32	3	(0.3)	3	0.38
Alopecia								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.31	2	(0.2)	2	0.23
Miliaria								
<8% (<64 mmol/mol)	0				3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.29	1	(0.1)	1	0.09
Hyperkeratosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.15
Hyperhidrosis								
<8% (<64 mmol/mol)	6	(0.9)	6	1.26	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	3	(0.3)	3	0.32
Dry skin								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	4	(0.3)	4	0.39
Rash erythematous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Blister								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acne								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Dermatitis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	5	0.55
Diabetic foot								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Erythema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Livedo reticularis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Night sweats								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Intertrigo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Angioedema								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Ingrowing nail								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Lipodystrophy acquired								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Myxoid cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Psoriasis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Skin exfoliation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Skin irritation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	1	(0.1)	1	0.08
Skin lesion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Urticaria contact								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Actinic keratosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Alopecia areata								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Asteatosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	4	(0.6)	4	0.80	3	(0.4)	3	0.52
>=8% (>=64 mmol/mol)	0				0			
Cold urticaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Decubitus ulcer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Dermal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.32
Dermatitis allergic								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Drug eruption								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Ecchymosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Granuloma annulare								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemorrhage subcutaneous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hidradenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lentigo								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Leukoplakia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Lipohypertrophy								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	0				0			
Macule								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Nail bed inflammation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Neurodermatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Pruritus allergic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Purpura								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Rash maculo-papular								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Rash papular								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Seborrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Skin discolouration								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				0			
Skin fissures								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Skin odour abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Skin reaction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Umbilical haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Urticaria thermal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Investigations								
All								
<8% (<64 mmol/mol)	29	(4.1)	36	6.59	23	(3.2)	26	5.31
>=8% (>=64 mmol/mol)	51	(4.3)	58	6.38	43	(3.7)	47	4.91
Weight increased								
<8% (<64 mmol/mol)	4	(0.6)	4	0.77	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	15	(1.3)	15	1.64	15	(1.3)	15	1.62
Blood creatinine increased								
<8% (<64 mmol/mol)	3	(0.4)	3	0.61	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.67	0			
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.61	0			
Blood alkaline phosphatase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.44	0			
Blood immunoglobulin E increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	2	(0.2)	2	0.16
Weight decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	0			
Occult blood								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Liver function test increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	1	(0.1)	1	0.08
Blood cholesterol increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Arthroscopy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Blood glucose fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Bone density decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Electrocardiogram abnormal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Electrocardiogram ST segment abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Electrocardiogram T wave inversion								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hepatic enzyme increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Low density lipoprotein increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.29
Prostatic specific antigen increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Transaminases increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Catheterisation cardiac								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eosinophil count increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Liver function test abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	2	0.29
Alanine aminotransferase increased								
<8% (<64 mmol/mol)	3	(0.4)	3	0.72	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Blood pressure increased								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Blood triglycerides increased								
<8% (<64 mmol/mol)	2	(0.3)	2	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.25
Glycosylated haemoglobin increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	2	0.16
Transferrin saturation decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Amylase increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Antinuclear antibody positive								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Blood creatine increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Blood creatine phosphokinase increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Blood glucose decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Blood glucose 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Blood potassium increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Blood pressure decreased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Blood urine present								
<8% (<64 mmol/mol)	1	(0.1)	3	0.40	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Body temperature increased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Breath sounds abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Carbohydrate antigen 19-9 increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cardiac murmur								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Cardiac stress test abnormal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Ejection fraction decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Electrocardiogram P wave biphasic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram repolarisation abnormality								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram ST segment depression								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Free fatty acids increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Glomerular filtration rate decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Grip strength decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Haematocrit increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Haemoglobin increased								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio increased								
<8% (<64 mmol/mol)	1	(0.1)	2	0.30	0			
>=8% (>=64 mmol/mol)	0				0			
Intraocular pressure increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Lipase increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lipids increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Monocyte count decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Monofilament pressure perception test								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Platelet count 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
QRS axis abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Red blood cell count decreased								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Thyroid function test abnormal								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Vitamin D decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vascular disorders								
All								
<8% (<64 mmol/mol)	26	(3.7)	30	5.53	22	(3.1)	24	4.16
>=8% (>=64 mmol/mol)	47	(4.0)	52	5.44	54	(4.6)	71	8.01
Hypertension								
<8% (<64 mmol/mol)	13	(1.9)	13	2.54	8	(1.1)	9	1.56
>=8% (>=64 mmol/mol)	19	(1.6)	19	1.97	27	(2.3)	31	3.55
Hypotension								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	2	(0.2)	2	0.17
Peripheral arterial occlusive disease								
<8% (<64 mmol/mol)	2	(0.3)	3	0.44	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	2	(0.2)	2	0.18
Arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	6	(0.5)	6	0.69
Blood pressure inadequately controlled								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Superficial vein thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Peripheral artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	5	0.61	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral coldness								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Arterial insufficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Varicose ulceration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Hot flush								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Venous stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Deep vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Diabetic vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	2	0.29
Hypertensive crisis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	2	(0.2)	4	0.54
Flushing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Haematoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Peripheral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Peripheral vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Peripheral venous disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.31
Varicose vein								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Aortic aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Aortic arteriosclerosis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.30	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.44
Aortic dilatation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Aortic stenosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Blood pressure fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Brachiocephalic arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.18
Hypertensive urgency								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	3	0.31
Iliac artery stenosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Intermittent claudication								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Macroangiopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Neovascularisation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Orthostatic hypotension								
<8% (<64 mmol/mol)	2	(0.3)	2	0.48	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peripheral artery aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Peripheral ischaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Phlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Thrombophlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Thrombosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	21	(3.0)	25	5.06	18	(2.5)	21	3.33
>=8% (>=64 mmol/mol)	30	(2.5)	37	3.92	33	(2.8)	43	4.44
Pollakiuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.52	1	(0.1)	1	0.09
Dysuria								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.48	2	(0.2)	2	0.24
Chronic kidney disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	5	(0.4)	5	0.49
Nephrolithiasis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	1	(0.1)	2	0.28
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	3	(0.3)	4	0.52
Renal impairment								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.32	2	(0.2)	2	0.17
Acute kidney injury								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	3	(0.3)	3	0.25
Diabetic nephropathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	2	(0.2)	2	0.29

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Chromaturia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Renal failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Urethral stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Nocturia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Proteinuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Renal cyst								
<8% (<64 mmol/mol)	6	(0.9)	6	1.27	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	4	(0.3)	4	0.39
Renal pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Ureterolithiasis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Urinary incontinence								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.28
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Urinary retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Haematuria								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.30	3	(0.3)	3	0.31
Calculus urinary								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Urine odour abnormal								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Bladder mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bladder prolapse								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Cystitis haemorrhagic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Hydrocalyx								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Hydronephrosis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Hypertonic bladder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Micturition urgency								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Nephropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Nephrotic syndrome								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Polyuria								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Pyelocaliectasis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Renal colic								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Renal mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Strangury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Stress urinary incontinence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Urinary tract disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Urinary tract inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Urinary tract obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	8	(1.2)	8	1.56	9	(1.3)	9	1.45
>=8% (>=64 mmol/mol)	25	(2.1)	27	3.02	21	(1.8)	21	2.28
Anaemia								
<8% (<64 mmol/mol)	4	(0.6)	4	0.68	5	(0.7)	5	0.79
>=8% (>=64 mmol/mol)	15	(1.3)	17	2.06	9	(0.8)	9	1.02
Eosinophilia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	1	(0.1)	1	0.15
Lymphadenopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Leukocytosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.24
Splenomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lymphadenopathy mediastinal								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Iron deficiency anaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.32
Polycythaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Thrombocytopenia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Blood loss anaemia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hypochromic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Leukopenia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Normocytic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Pancytopenia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Thrombocytosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	15	(2.2)	15	2.56	9	(1.3)	11	2.17
>=8% (>=64 mmol/mol)	21	(1.8)	25	2.59	28	(2.4)	28	3.21
Insomnia								
<8% (<64 mmol/mol)	5	(0.7)	5	0.84	2	(0.3)	3	0.64
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.61	4	(0.3)	4	0.42
Depression								
<8% (<64 mmol/mol)	3	(0.4)	3	0.42	0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.54	9	(0.8)	9	1.01
Anxiety								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	3	(0.3)	3	0.25
Sleep disorder								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.25	2	(0.2)	2	0.29
Agitation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Drug abuse								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Irritability								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Listless								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Post-traumatic stress disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Stress								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Depressed mood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Nightmare								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Adjustment disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Adjustment disorder with depressed mood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Adjustment disorder with mixed anxiety and depressed mood								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Affect lability								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Anxiety disorder								
<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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Bruxism								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Disorientation								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Drug dependence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Emotional distress								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Fear								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.30
Major depression								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Mental status changes								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Mixed anxiety and depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Mood swings								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Persistent depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Phobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	8	(1.1)	8	1.42	7	(1.0)	9	1.56
>=8% (>=64 mmol/mol)	21	(1.8)	21	2.20	16	(1.4)	18	1.70
Erectile dysfunction								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.48	1	(0.1)	1	0.14
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	2	(0.2)	2	0.17
Intermenstrual bleeding								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.30	0			
Breast pain								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Prostatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Ejaculation failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Menstruation irregular								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pelvic discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Breast mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Ovarian cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Uterine polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Uterine prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Vulvovaginal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Atrophic vulvovaginitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	1	(0.1)	1	0.14
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cervical polyp								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Colpocele								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Dysmenorrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Galactorrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Genital prolapse								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Menopausal disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Menopausal symptoms								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Menstruation delayed								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Penile rash								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.27
>=8% (>=64 mmol/mol)	0				0			
Prostatic calcification								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Pruritus genital								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.23
Testicular cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Uterine enlargement								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vaginal discharge								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Vaginal haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.16
Vulvovaginal dryness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	12	(1.7)	14	2.41	9	(1.3)	12	1.87
>=8% (>=64 mmol/mol)	19	(1.6)	25	2.66	18	(1.5)	28	2.97
Adenocarcinoma pancreas								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Eye naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	3	0.31	0			
Metastases to liver								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			
Pancreatic neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Bladder papilloma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Lung cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.08
Skin papilloma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Chronic myeloid leukaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Colon adenoma								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bladder cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Invasive ductal breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Invasive lobular breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Lipoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Pancreatic carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Small cell lung cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Acrochordon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Neoplasm skin								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Oral fibroma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Salivary gland neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Seborrhoeic keratosis								
<8% (<64 mmol/mol)	1	(0.1)	2	0.30	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Adenocarcinoma of colon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Adrenal adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Basal cell carcinoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	3	(0.4)	3	0.41
>=8% (>=64 mmol/mol)	0				0			
Benign renal neoplasm								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Bowen's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Breast cancer								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Breast cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Colon cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Colon cancer stage II								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Colorectal cancer								
<8% (<64 mmol/mol)	2	(0.3)	2	0.37	0			
>=8% (>=64 mmol/mol)	0				0			
Dysplastic naevus								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Endometrial adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Gastric cancer								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal tract adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Glioblastoma multiforme								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Haemangioma of liver								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatocellular carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Invasive breast carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Lung adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Lymphangioma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Malignant melanoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Malignant melanoma in situ								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Malignant peritoneal neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Metastases to bone marrow								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Metastases to lymph nodes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Myxoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Osteoma								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Prostate cancer								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Prostatic adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Renal cell carcinoma								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Renal hamartoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Renal neoplasm								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Small intestine neuroendocrine tumour								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Squamous cell carcinoma of skin								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Uterine cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				3	(0.3)	3	0.32
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	13	(1.8)	13	2.33	8	(1.1)	8	1.53
>=8% (>=64 mmol/mol)	13	(1.1)	16	1.52	14	(1.2)	15	1.67
Vertigo								
<8% (<64 mmol/mol)	6	(0.9)	6	1.07	2	(0.3)	2	0.27
>=8% (>=64 mmol/mol)	4	(0.3)	5	0.54	6	(0.5)	7	0.80
Ear pain								
<8% (<64 mmol/mol)	3	(0.4)	3	0.61	0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	1	(0.1)	1	0.15
Tinnitus								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.17	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypoacusis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	3	(0.3)	3	0.25
Deafness bilateral								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
External ear pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Meniere's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Vertigo positional								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Ear inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Eustachian tube dysfunction								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Cerumen impaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Deafness unilateral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Ear discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Middle ear inflammation								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Motion sickness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Presbyacusis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			

Hepatobiliary 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
All								
<8% (<64 mmol/mol)	9	(1.3)	11	1.99	8	(1.1)	10	2.13
>=8% (>=64 mmol/mol)	10	(0.8)	14	1.42	13	(1.1)	15	1.45
Hepatic steatosis								
<8% (<64 mmol/mol)	3	(0.4)	3	0.54	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	5	(0.4)	5	0.42	6	(0.5)	6	0.56
Hepatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.2)	2	0.23	0			
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.38
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Gallbladder polyp								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Cholelithiasis								
<8% (<64 mmol/mol)	2	(0.3)	2	0.29	0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Cholecystitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.15
Gallbladder cholesterolosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypertransaminasaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	2	0.17	0			
Alcoholic liver disease								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Bile duct stone								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	2	0.16
Biliary colic								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Biliary dyskinesia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Cholecystitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatic cirrhosis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hepatic cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hepatic mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.13	0			
>=8% (>=64 mmol/mol)	0				0			
Hyperplastic cholecystopathy								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	0			
>=8% (>=64 mmol/mol)	0				0			
Liver disorder								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	0				0			
Non-alcoholic steatohepatitis								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Nonalcoholic fatty liver disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.17
Steatohepatitis								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Immune system disorders								
All								
<8% (<64 mmol/mol)	6	(0.9)	7	1.32	6	(0.8)	7	1.39
>=8% (>=64 mmol/mol)	6	(0.5)	6	0.63	9	(0.8)	9	1.08
Seasonal allergy								
<8% (<64 mmol/mol)	4	(0.6)	4	0.68	3	(0.4)	3	0.63
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.39	5	(0.4)	5	0.56
Food allergy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Drug hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Allergy to arthropod bite								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.29
Allergy to arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Anaphylactic reaction								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Hypersensitivity								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	0				0			
Immunisation reaction								
<8% (<64 mmol/mol)	0				1	(0.1)	2	0.27
>=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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	2	(0.3)	2	0.39	2	(0.3)	2	0.39
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.53	3	(0.3)	3	0.25
Type V hyperlipidaemia								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	3	(0.3)	3	0.38	0			
Corneal dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Atrial septal defect								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Congenital syphilitic osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Cystic fibrosis lung								
<8% (<64 mmol/mol)	1	(0.1)	1	0.24	0			
>=8% (>=64 mmol/mol)	0				0			
Hydrocele								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	0			
>=8% (>=64 mmol/mol)	0				0			
Hypertrophic cardiomyopathy								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				0			
Myotonic dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Endocrine disorders								
All								
<8% (<64 mmol/mol)	2	(0.3)	2	0.40	6	(0.9)	6	1.15
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.40	12	(1.0)	12	1.21
Autoimmune thyroiditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Hypothyroidism								
<8% (<64 mmol/mol)	1	(0.1)	1	0.25	1	(0.1)	1	0.25
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	3	(0.3)	3	0.25

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypogonadism								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Thyroid mass								
<8% (<64 mmol/mol)	1	(0.1)	1	0.15	1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	1	(0.1)	1	0.14
Adrenal mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Adrenocortical insufficiency acute								
<8% (<64 mmol/mol)	0				2	(0.3)	2	0.49
>=8% (>=64 mmol/mol)	0				0			
Goitre								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.14
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hyperplasia adrenal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hyperprolactinaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Hyperthyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.2)	2	0.17
Inappropriate antidiuretic hormone secretion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Secondary hypogonadism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline HbA1c group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	4	(0.3)	4	0.46	5	(0.4)	5	0.49
Cardiac pacemaker replacement								
<8% (<64 mmol/mol)	0				1	(0.1)	1	0.24
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Shoulder operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Tooth extraction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.15	0			
Knee operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.1)	1	0.08	0			
Large intestinal polypectomy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Removal of foreign body								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.09
Skin neoplasm excision								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Spinal operation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.08
Toe amputation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.15
Social circumstances								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14
Menopause								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.1)	1	0.14

%: 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), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of 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, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.